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IMPRESSIONS

PEACE THROUGH CHEMISTRY I (1960)
ROY LICHTENSTEIN (1923)

Perhaps no single painter better represents the basic premises of the Pop Art movement than Roy Lichtenstein. This month’s cover of JMCP features an early work by the artist which displays the style, context, and medium that would distinguish this school of American modern art prevalent in the 1950s and 1960s. This oil and acrylic composition is patterned after a WPA (Work Projects Administration) mural that was popularized both in the United States and in Britain during the Roosevelt administration’s New Deal efforts. Its motif incorporates images representative of the ideal of peace, the power of science and industry, and the ingenuity of human activity in a triptych of angular lines, flat colors, and Ben Day dots. The work conjures up an Art Deco theme that evokes faith and enthusiasm in the modern scientific/industrial age of the time. The result is a hard-edged subject painting that documents while it gently parodies a familiar image.

Lichtenstein is recognized more immediately for his striking, oversized, painted reproductions of comic strip characters rendered with extreme precision in the newsprint style. In these later pieces, he dealt in the standardized imagery of traditional comic strips devoted to violent action and sentimental love. The focus was always limited to a singular, emotive character, who was virtually immortalized by the single mindedness of the presentation. These paintings are curiously unreproducible, as they return to their original medium when printed. In the paint medium, his images of printed materials pose artistic challenges in composition that are not readily anticipated nor easily reconciled. Painting the colored dot format familiar in comics requires a full reconsideration of detail. The pictures are not mechanical copies, but interpretations that remain faithful to the spirit of the original through countless adjustments of content, line, and color.

These images are fascinating because they reveal the rigid conventions of their sources, as unfailike as those conventions are, and yet, they are potently communicable. Though accurately depicting familiar objects, we are aware that the work is also a feat of imagination, and it is Lichtenstein’s imagination that surprises. When applied to a reinterpretation of other historical works, as was typical of the Pop Art movement, the effect is astonishingly powerful.

ABOUT THE ARTIST

Lichtenstein was raised on the Upper West Side of Manhattan, in a fairly affluent household. Paradoxical to the disruption that his work would inflict on the art world, he was an ideal child. Lichtenstein has questioned whether his attitudes may have been a little strange. “I did all the normal things, nominally.” He attended a private academy in Manhattan during his teen years, graduating in 1940. He alternately showed an interest in drawing and science through his youth, but enrolled in the Art Students League upon graduation.

In pursuit of a degree that would qualify him to teach, he enrolled in Ohio State University, which had a large and well-established art department. There, he was educated in a mixture of science and aesthetics using a technique that relied on images fleetingly flashed on a screen. Drawing such impressions taught him the relation of the parts of a composition to the whole—the “perceptual unity.” His education was disrupted by WWII, when he served in an engineers battalion throughout Europe. Upon returning to the U.S., he quickly completed his MFA degree at his alma mater in 1949 and stayed on as an instructor for two years.

Although a recognized artist with exhibits in New York City (his work at that time was derived from the abstract expressionists), his career path led him through employment in industrial product development, drafting, and window display design. Eventually securing a teaching position at the State University of New York at Oswego from 1957-60, he began experimenting with what would become his signature style in the obscurity of upstate New York. It was not until he was invited to the faculty of Douglas College in New Jersey in 1960 that he was indoctrinated into the amorphous group of artists that would become the Pop Art school, including George Segal, Claes Oldenberg, Robert Rauschenberg, and the musician John Cage.

POP PERCEPTIONS

Lichtenstein’s paintings are based on the imagery of the American mass media. Although descended from the concepts of Duchamp, Pop, unlike the preceding Dadaists and abstract expressionists, is not motivated by despair at present day civilization; instead, it views commercial culture as its raw material. It embraces common culture rather than antagonizes it and, in that fashion, is “postmodern” rather than anti-modern. The style attempts to integrate art and life by examining the images that surround us with an intensity and penetration that frequently makes us conscious of them for the first time. This same type of insight and enthusiasm may prove inspirational during the transition of our American medical system.

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PHILOSOPHICAL CONFLICTS IN FORMULARY MANAGEMENT

You are managing a pharmacy benefit for a large staff-model HMO under a semiclosed formulary. Your immediate goal is to avoid large, future annual costs in medication treatment. At the same time, integrated care initiatives are empowering physicians (at least on paper), and feedback is being provided on cost so that they are held accountable for all costs associated with the care of their patients. These accounting structures are set up under a capitated budget. Information is streaming to the physicians about their costs specific to various care- or cost-target areas. As the physicians are learning about how costs are affected by the decisions they make in providing care, they are feeling a sense of loss or hopelessness as they are being directed by health care administrators and benefit management personnel to make decisions that affect the clinical quality of care provided to their patients.

Control versus empowerment: two seemingly mutually exclusive goals that create a conflict in formulary management in today's health care environment. As health systems move from departmentally focused segregated cost and management structures with the support of new technology, information systems, and patient-care-tracking methods, a unique set of conflicts for managing cost is created for pharmacy benefit issues in managed care.

The level of control needed to manage costs effectively in the past has been asserted through on-line claims adjudication systems, and utilization review performed by benefit management and clinical pharmacists working primarily with physicians providing the service under independently managed health care plans. Because of the confusion created by the different formularies under which pharmacists and physicians are required to perform, difficulties arise in communication and customer service relationships.

BALANCING BUSINESS WITH CARE

The sense of control needed by the person paying the bill, the benefit management company, or insurer is certainly an important and valid need, but balance is necessary to create a better customer service relationship as well as to empower physicians and pharmacists providing care and making decisions within current structures. The dichotomy of fee-for-service versus capitated systems creates a unique paradox requiring thought as to how these issues are managed.

In the example shown at the beginning of this article, the primary conflict for physicians is with the value system they bring to health care. Health care professionals by definition are personally invested in their profession and have a difficult time reconciling personal with organizational values. As a result, their values focus on compassion, caring, and resolution of health care complaints. These conflict with the “business” focus being created by the increasing pressure in the marketplace today, as communicated by benefit managers.

Following the scenario further, suppose that the managers have three months to accomplish and implement plans that will produce this enormous cost-saving, cost-avoidance goal. The choices are there: two competing interests, two competing goals. Should managers continue to allow physicians to work somewhat autonomously, giving them information, holding them accountable for the decision-making process?

This dilemma presents itself under a number of different fact patterns and scenarios each month in the hundreds of managed care organizations in this country. Whether through network relationships, or as employees in managed care organizations, physicians are in serious personal conflict and feel that they are compromising their own deeply held values daily to meet their employers' demands. Those feelings are not lost on the patients, as physicians create patient dissatisfaction with and disillusionment about the organization through passive-aggressive behavior and direct communication.

Patients come into the system with the belief that their health care organization has some maternal or paternal characteristics. The feedback they receive, both passively and actively from providers, creates further disillusionment about the commitment of their health care provider.

GETTING PHYSICIANS ON BOARD

The issues around formulary management are much more complex than just trying to keep drug costs down. They can result in an enrollee and customer dissatisfaction and loss of revenue as a result of voluntary disenrollment in each program.

The bottom line is how can pharmacy benefit managers work within the current environment to accomplish very aggressive cost-reduction goals and still create an environment in which physicians are empowered? How can managers create a safe place for both providers and patients?

Many benefit-management companies—through closed formulary policies and prior authorization procedures—have established clear guidelines for what drug products can and cannot be used. This gives physicians a safe haven, emotionally, in their communication with patients. However, it shifts control and accountability to the "organization" and away from the person providing the care. Physician empowerment, created both clinically
and economically and supported by feedback and information, meets the need of physicians to have that control locally while still accomplishing the cost-saving goals defined by the benefit-management company.

Can organizations afford to wait to accomplish their cost-saving goals by focusing on long-term needs, or is health care in an environment that requires immediate action? Should managers take control for making decisions and enforcing those decisions through strict adjudication policies and procedures?

Are physicians on board? Many are being forced to respond to the marketplace economics because of the need to stay in business themselves. The shift from health care delivery to business-focused health care management is requiring physicians to respond. A number of questions have been raised about whether prior-authorization procedures have been effective in truly keeping costs down, or if utilization-management review and feedback to physicians, including drug switching, has been effective. Certainly the conflicts and barriers ripe in this environment are apparent, and everyone who has worked to some degree in this environment has felt the pressure, heard the feedback, tried to deal through academic detailing, utilization management, and clinical support for the decisions that are involved in medication management therapy. The real question is whether we can afford to wait? The challenge is to provide information to physicians and structure it so they can make the decisions within organizational goals, including cost containment.

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Can a health care model in which employees choose—and pay for—their own health care revolutionize the industry? Let's look at the bellwether state of Minnesota to find out.

The health care revolution has been proceeding nicely in Minnesota, where many aspects of health care reform have been incorporated into the new system for several years now. However, a funny thing happened along the way: Big business jumped ship and set up its own approach to solving emerging problems.

In the new model, key large Minnesota employers are empowering hundreds of thousands of their workers to do something unique: pick their own health plans and pay their own premiums. Coupled with a uniform benefit design, the model will enable patients to do what health care systems in the U.S. have rarely accomplished: To choose their own providers based on their own ideas about service, cost, and customer satisfaction.

What is the Minnesota Buyers Health Care Action Group (BHCAG) and what is it doing about problems with the state's integrated service networks (ISNs; see sidebar on next page)?

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What do these changes mean for managed care groups and their employees? Let's take a look at recent developments in this key testing ground for the health care system of the twenty-first century.

**BHCAG: LOOKING FOR INCENTIVES, ACCOUNTABILITY**

Steve Wetzell, executive director of BHCAG, is quick to point out the problems that the group is trying to solve. He begins by showing the diagram in Figure 1. He follows with concerns about the current features of the health care delivery system—one he readily admits his members helped to design.

▲ The incentive is for health plans to build large, overlapping networks.
▲ Health plans maximize premiums and minimize provider payment.
▲ The health care provider market share is driven by payer relationships.
▲ The plan-wide "premium" undermines provider accountability in that inefficient or expensive providers are invisible to the payer.
▲ Providers do not "own" or advocate the plan.
▲ Conflicting rules are imposed on a provider by competing health plans.
▲ Provider networks are not stable as plans and plan designs constantly shift.
▲ Fragmented data are created.

BHCAG views integration of health systems, vertical or otherwise, as being devoid of two essential ingredients: market incentives and accountability. As payers, they want to change the incentives in the health marketplace. By developing a system of direct contracting with providers, they hope to enable providers to create care systems for service provision by providers and health plans functioning in new roles. Figure 2 shows the care systems BHCAG is trying to incent the providers to create.

**NEW CARE SYSTEMS**

The elements of the improved model BHCAG would create include the following:
▲ A single administrator and standard plan design.

**LEADING A LARGE EXPERIMENT**

The consolidation of Minnesota's managed care market was an inevitable consequence of the past four years of health reform legislation. The cornerstone of Minnesota's reform was new health organizations called Integrated Service Networks (ISNs). These large health conglomerates were fashioned after the concept of "managed competition," the brain child of the Jackson Hole group so influential in the Clinton Administration's failed effort at health care reform. ISNs were designed to be vertically integrated, self-contained health systems similar to HMOs—only larger. Jackson Hole's leader, Paul Elwood, envisioned that ISNs would compete against each other in a system intended to become the U.S.'s response to the international move to single payer or nationalized health care. Minnesota is leading the way to test this large experiment in health reform.

Enabled by MinnesotaCare, Minnesota's managed care systems rapidly consolidated into what became known as the "Big Three"—Allina, HealthPartners, and Blue Cross and Blue Shield of Minnesota. Their domination of the health delivery system should have been no surprise to those leading or following Minnesota health reform. The business community was an enthusiastic participant in the rush to these new systems, participating with hopes of stopping the double-digit health care annual inflation decreasing their bottom line.

The Minnesota Buyers Health Care Action Group (formerly Business Health Care Action Group or BHCAG) startled many in the vanguard of Minnesota health policy when they recently announced a major concern about this consolidation in the health marketplace. They made the front page of the Wall Street Journal, stating that their new strategy would be to contract directly with health care providers. The major Minnesota news outlets issued a number of stories about the abrupt about-face of this influential business health purchasing group, which may have the marketplace clout to make some of these changes occur.

Just who is involved in this group and what are they attempting to accomplish? BHCAG is a coalition of 24 large Minnesota-based employers providing health care for 250,000 employees, retirees, and their dependents. Minnesota state employees joined BHCAG, prompting the name change to Buyers Health Care Action Group. When Cargill, Dayton Hudson, General Mills, and 3M speak, everyone listens. These self-insured ERISA companies employ 10% of the Minnesota metropolitan market and 5% of those living in the upper midwest region of the U.S.

The emergence of this group and their criticism of the Minnesota health care reform effort has left executives of managed care organizations in a difficult dilemma. The ISNs were formed in response to encouragement by Minnesota health policy leaders, including members of the business community now criticizing them because of their size and business strategies. One thing is clear—the rules are changing dramatically since BHCAG made the announcement about their change in strategy.

▲ Consumer contributions based on the relative cost of competing care systems.
▲ Standard risk adjustment with the care systems at risk.
▲ Providers contract with plans for value-added services.
▲ Employer-designated centers of excellence.

▲ Standardized cost, quality, and service information.

BHCAG envisions that this fundamental role reversal will challenge health plans in these ways: "In today's managed care markets, health plans possess the power. All dollars flow..."
through the plan. The plan decides who is in the network. The plan generally sets practice standards. In the new model, dollars flow directly to care systems. Accountability for quality, cost, and service is at the care system level. Health plans will need to accept a loss of control over the market and determine how they can bring value-added services to purchasers and providers to support care systems."

Improved incentives envisioned in the BHCAG systems include these:

- Providers advocating their product (i.e., the care systems) through which they serve the BHCAG employees.
- A provider care system market share driven by efficiency, quality, and service, a truly competitive marketplace model.
- Network stability in the marketplace.
- The health plans providing value-added services to provider care systems.
- Consumers driving the market.

**IDENTIFYING THE PRACTICAL ANSWERS**

BHCAG recently released a request for proposal that provides some interesting glimpses into the future of the new role of managed care systems and health care providers. BHCAG wants to change their buying model to create a market more directly driven by consumers and provider responses to the needs of consumers. Consumers will be able to choose among Care Systems (integrated teams of providers) according to their cost, who their providers are, and their performance in areas of quality and customer service.

This coalition of business pur-

chers sees their new approach as an improvement and the next logical step in the evolution of its program, which they are calling Choice Plus.

Beginning in 1997, BHCAG will contract directly with multiple “Care Systems,” and enrolled employees will each choose one of them.

A Care System is a primary-care-centered health system (family practice physicians, pediatricians, internists) with its affiliated specialty, hospital, and allied professional arrangements. It is organized to provide (or contract for) the full continuum of medically necessary services for an enrolled population.

One of the more revolutionary concepts is that each primary care provider can participate in only one Care System. Primary care providers will have to select their strategy and partners carefully.

Pricing and performance information for consumers will be organized around Care Systems. Consumers may continue to identify their provider choice with a particular clinic, but they should quickly become familiar with the term Care System.

**GETTING INFORMATION WITH WHICH TO MAKE DECISIONS**

So how will employees make these informed choices? BHCAG will provide its employees and dependents with a wide range of comparative information about their Care Systems and the providers within them. This information will be of three types:

- **Descriptive information** on the Care System and on the particular clinics within each Care System, including location, hours, and on-site services available plus information on individual physicians (training, certification, statements of philosophy, languages spoken). Also included will be information on specialist referral and hospital relationships.
- **Comparisons of quality** at the Care System level, including both clinical measures of technical quality and patient-reported measures of care quality.

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AN OPPORTUNITY FOR PHARMACY

The direct contracting model creates a wonderful opportunity for pharmacists in managed care, hospital, and community pharmacy to redesign their relationships to focus on the comprehensive pharmaceutical care of their patients. The elimination of barriers to caring for the drug-related problems in each patient can open whole new vistas of cooperation and partnerships between pharmacists in each of these practice settings. The new systems seem well designed for focusing on the elimination of these expensive and potentially dangerous drug-related problems currently undetected by pharmacists in any system or practice setting. Make no mistake about this fact—these business folks mean business. Those providers not paying attention will wonder where the patients went!

The price competition is envisioned to work as follows. BHCAG employers will remain self-insured. Care Systems will submit target per member, per month rates for a standard population and set of covered services. Differences in Care System target rates will be reflected directly in premiums paid by Choice Plus enrollees, who will generally select a plan once a year. Each BHCAG employer will be responsible for whatever shortfalls or surpluses arise when the actual fee-for-service cost of care for their enrollees is different from the BHCAG employer's premium contribution plus the members' premiums.

WHERE WILL THIS ROAD LEAD?

Keep close tabs on what happens with this system in Minnesota. A Business and Health October 1995 cover story pointed to the Minnesota BHCAG direct-contracting initiative as the possible next step in health care management in response to HMO consolidation, speculating that further market consolidation will likely result. Direct contracting has gained national attention, and employer groups in other states will be watching from outside while those pharmacists, physicians, and nurses employed in Minnesota managed care organizations watch the revolution from the inside.

References

Innovations in Quality Improvement: Managed Care Leads the Way

Improving quality—and proving things are better—has become the domain of managed care organizations, including PBMs. This article contains snapshots of some innovative quality improvement programs introduced by organizations in managed care.

Higher quality health care springs from sound data. Managed care organizations are structured to collect and evaluate data as part of their mission. Thus, managed care organizations (MCOs) are leading the way in quality improvement in health care nationwide. Not only is the difficult quest for improved care a goal, but many organizations also are finding ways to demonstrate lower costs of care.

Stephen Lash, Pharm.D., who is a director on the Board of AMCP, says that quality, as defined in contemporary terms, is compliance to an accepted standard. Quality improvement should be a concrete and unchanging goal.

“The concept of quality improvement is intact, but whether people are getting better at measuring it, is something else,” Lash says. “I hope that the concept of quality improvement is not just a fad that comes and goes. ‘Out-

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comes measurement was really the buzzword a few years ago, and now it is 'disease management.' My fear is that quality measurement is something that might go out of fashion."

Quality improvement rests on the ability to demonstrate in concrete terms that some condition or situation has gotten better. "If you are treating people's hypertension, and you change their treatment so that the disease is managed better, so that the patient is healthier and happier, hopefully such a standard and process won't come and go," he says. Employers more frequently are consulting and contracting with disease management firms, which primarily seek to reduce costs of care, says Lash.

The National Committee for Quality Assurance (NCQA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are the two major groups helping to evaluate quality and accredit organizations that strive for higher quality (see JMCPI, Vol.1, No. 1, pp. 40-51, for a review of the concept of quality and processes of quality assurance, including the DUE model advocated by JCAHO).

The NCQA is a private, not-for-profit organization that both assesses and reports on the quality of managed care plans. Quality improvement is one of six areas in which NCQA accredits these plans. Briefly, NCQA seeks to learn the following:

▲ If the plan fully examines the quality of care given to its members;
▲ How well the plan coordinates all parts of its delivery system;
▲ What steps a plan takes to ensure that members have access to care within a reasonable period of time; and
▲ What improvements in care and service the plan can demonstrate.

Some pharmacists complain that there are no explicit indicators for pharmacy procedures among the NCQA indicators of quality. Lash, director of clinical services for Wellpoint Pharmacy Management, a division of Blue Cross of California, says that there is "absolutely no need for pharmacy indicators." Lash maintains that "many pharmacy programs, projects, and processes fit beautifully into the way NCQA has crafted its indicators."

Lash says that most other disciplines in medicine "can't create the measurements that pharmacy can, because of the powerful databases that run the pharmacy systems. Pharmacists can make incredibly accurate measurements of potential drug interactions, allergies, duplicate therapies—lots of things require chart review, but a lot of things that pharmacists do can be done with great accuracy and power in the databases." Then pharmacists can make interventions and measure again. If things have improved, that is a powerful tool to put into the NCQA documentation for official review. Lash says.

Barry Scholl, an NCQA spokesman, says that the organization's quality improvement standards require that there be "a real operational quality improvement at the health plan, and that there is documentary evidence that both describes the program and outlines its successes." If a program involving pharmacy "falls under the domain of a quality improvement or a quality management program, then it is something that NCQA would consider" in its accreditation process, Scholl says.

NCQA is always "open to communicating with any health plan that has been involved in the organization's accreditation process or that hopes to go through that process," Scholl says. Participants receive NCQA publications, a copy of standards, the guidelines that reviewers use—all of these things put together constitute a roadmap to what NCQA is looking for, Scholl says.

The JCAHO has begun to accredit health care networks, including HMOs, PPOs, PHOs, IPAs, and other integrated networks. JCAHO standards for health care networks include issues that cover patient rights, organization ethics, continuum of care, patient education, information management, and other areas.

THE MANAGED CARE ADVANTAGE

At Rocky Mountain HMO in Grand Junction, Colo., ideas for quality improvement come from medical literature, the needs of members and providers, and local issues. "It is important to focus on what is meaningful and measurable," says Nanette Emerson, R.Ph., a clinical pharmacy specialist with Rocky Mountain. Emerson, with her hospital background, says that hospitals and HMOs think in different terms. "Certainly hospitals are concerned with safety and costs, but their approach is different from that of an HMO."

Most often, an HMO or MCO will accomplish quality objectives by searching and sorting a powerful and extensive database. "I think that is second nature to HMOs," Emerson says. "Data are very valuable and HMOs understand that."

Lash agrees. "Pharmacy's strength is that we have data. The pharmacy databases are extremely powerful and accurate when you compare them with medical databases, which are subject to coding variations, and are very subjective." He cautions that pharmacists must also visit with patients and review charts, "but we have a big advantage just with our databases," which can measure medication dosing forms, dosing times, and other aspects of care involving medications.

PBMS HELP OTHERS HELP THEMSELVES

Pharmacy benefits management firms (PBMs) offer powerful computer resources that can assist MCOs in their quest for improved quality. Rocky Mountain has worked in tandem with its PBM to perform and track some of its quality studies. "Our PBM has a lot of clinical programs and computer capabilities in place," Emerson says. She says that Rocky Mountain HMO and its PBM tailor computerized programs so

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that the HMO can best use information. For example, Rocky Mountain recently examined its members who use a high volume of controlled substances. The PBM provided a basic program that was tweaked to suit Rocky Mountain HMO's needs.

PBMs are becoming very active both in quality improvement initiatives and disease management programs. While reducing the cost of care is an important aspect of PBM programs, reducing the cost of pharmaceuticals is not necessarily the goal. In the September-October 1995 issue of *Pharmacotheraphy*, a report sponsored by Diversified Pharmaceutical Services, a Minneapolis-based PBM, noted that if the entire medical picture were analyzed, use of more expensive drugs in some cases might lower total direct medical costs: “The availability of information to demonstrate differences, if any, in total treatment costs between two agents would considerably enhance therapeutic decision-making and would guide treatment by an outcome-based drug formulary. The question that requires an answer is centered on the value equation:

\[
\text{Value} = \frac{\text{Outcomes}}{\text{Cost}}.
\]

Before paying more for drug A than for drug B, the payer will demand to see value. When available, direct and indirect cost information will be applied to position drugs appropriately in a drug formulary.”

Some PBMs have embarked on multiple generations of quality improvements initiatives. For example, in 1994, PCS Health Systems announced an ongoing initiative called the PCS Generic Performance Incentive (GPI) program, which initially attracted 71 plan sponsors who agreed to implement the program. This program gave pharmacists the opportunity to dispense appropriate generic prescription drugs and become eligible for incentive payments. During July, August, and September 1994, the first quarter year of the initiative, the generic dispensing rates were assessed as showing “minimal improvement” over the baselines in each state. Performance and “missed opportunities” reports were issued after the first-quarter results. GPIs primary purpose is to demonstrate the impact of generic counseling and other cognitive services on the cost-effectiveness of a prescription drug benefit.

Doug Stephens, Vice President of Network Administration for PCS, reports that the GPI has been a success in two ways. Today more than 8 million people are enrolled in that program. “The result is client-specific, based on where they were going in the program,” Stephens says. “If they came in with a low generic dispensing percentage initially, we found that it did have a significant impact. We found increases in generic substitution 2–4% higher than we would have expected without the GPI.”

GPI’s success was slated to lead to a new program called the Performance Network. The network consists of pharmacies that have agreed to align their own incentives and goals with those of PCS’s customers and improve performance to reduce drug costs. These pharmacies are encouraged to take a more active role in patient counseling and have agreed to be evaluated against a set of criteria that measures their performance in such areas as purchasing practices, generic substitution, and usual and customary pricing.

Pharmacists receive incentive fees if they improve performance above the baseline for their geographic area. A fee is deducted if performance falls below baseline in any calendar quarter. The Performance Network is “an opportunity for both independent pharmacies as well as pharmacy chains to make a difference and to be rewarded for their efforts,” says Steve Geringer, President and Chief Executive Officer of PCS. Performance Network, along with a Performance Drug List, and Performance Interventions, comprise the Performance Rx program to ensure appropriate clinical results for patients and control costs.

PCS has also turned to disease management initiatives, as presaged in the initial GPI report. Since then, PCS has assumed responsibility for its pharmaceutical owner Lilly’s Integrated Disease Management group, with its outcomes-based measures. One PCS representative says that the company looks at outcomes to “continuously improve what we have implemented and to measure a difference” in many disease states, including asthma, diabetes, depression, hypertension, gastro-esophageal reflux disease, and peptic ulcer disease.

**DISEASE MANAGEMENT SPARKS QUALITY IMPROVEMENT INITIATIVES**

The largest disease management organizations are concerned with improving the care and costs of asthma, hypertension, diabetes, and estrogen-replacement therapy, among other diseases.

“Everyone is managing asthma, because you can turn around an asthmatic almost immediately and see changes in hospitalization rates,” Lash says. “An asthmatic who is not being treated well can, within days or weeks, be turned around.” A diabetic requires more time and effort, but diabetes swallows so much money that it is one of the big topics, Lash says. Likewise, hypertension and estrogen-replacement therapy have “down the road” payoffs.

Congestive heart failure, which accounts for most of the hospitalizations in the country, is a good candidate for better management, but "probably the huge dollars involved in CHF involve the employer more in terms of productivity, so the focus of CHF programs originates with employers," Lash says.

Certain types of patients with CHF are candidates for an added ACE-inhibitor to their drug regimen, says Cynthia Figg, R.Ph., M.H.A., who was promoted recently within CIGNA HealthCare, where she had been Director of Regional Pharmacy Services in Richmond, Va. “This helps get to patients out of the hospital, gives them better quality of life and longevity.” Following published recommendations for certain cardiac patients, CIGNA specialists reviewed the data-

*Continued on page 27*
base for patient criteria, and mailed letters to all relevant physicians, citing articles and suggesting that they evaluate their patient for an ACE inhibitor, with patient name and information.

Since the mailing, CIGNA has followed up to learn how many patients have received an ACE inhibitor, but the data were not finalized at press time.

Similarly, studies have shown that certain diabetic patients also may benefit from an ACE inhibitor. CIGNA again identified patients, based on their drug histories, who would fit the criteria for those that might benefit from that drug addition.

At Rocky Mountain HMO, the focus of a quality initiative may be to impact overall medical quality and cost or may be more specifically directed toward pharmaceutical use.

One of the specific pharmaceutical initiatives undertaken involved patients with severe asthma who use high quantities of β-agonist drugs. Rocky Mountain HMO evaluated these patients to learn which patients did not receive concurrent inhaled steroids, because the combination of drugs is much better for management of that disease. "You want to identify the members who are not receiving the second drug, and get them started on it," Emerson says. "This combination might help them to avoid doctor visits, emergency room visits, and hospitalizations. If you're looking at this with blinders on, you would only see pharmacy budget expenditures increase for those members, but looking at the big picture, it results in healthier members."

Looking at both quality and cost improvement, Rocky Mountain has recently studied the use of H2-receptor antagonist drugs, which the members may take chronically. Initially these products are started out at an acute dose for 6–8 weeks, then reduced to a lower ("maintenance") dose. It is common, however, for patients simply to continue at the acute dosage level. By retrospectively reviewing their claims data, Rocky Mountain HMO was able to identify patients whose dosage had not been reduced.

"We were then able to provide physicians with the names of their patients who were candidates to have their dosage reduced. This results in a cost savings, which at the same time improves quality by not exposing patients to a higher dose of medication than is necessary," according to Emerson. Rocky Mountain and their PBM examines pharmacy claims data for quantities of the medication, estimating the dosage based on prescription quantities, when the prescription was filled, and how many times and when it has been refilled, Emerson says. "Then our associate medical director and I sign a letter that goes out to the physicians who have had patients identified by the study, reminding them of the suggested course of therapy, H. pylori treatment, and so on."

MENTAL HEALTH TREATMENT QUALITY MEASUREMENTS COME OF AGE

Pigg says that the mental health arena, including substance abuse, is another area ripe for quality explorations.

CIGNA's subsidiary, MCC Behavioral Care (MCC), a national managed care company based in Minnesota that provides mental health, substance abuse, and employee assistance services, has been developing and refining its Clinical Quality Information System (CQIS) since 1992. John Bartlett, M.D., then MCC's Vice President and Corporate Medical Director, assumed the job of creating a way to measure outcomes of MCC's mental health and substance abuse services. Bartlett envisioned a continuous process for outcomes data collection, analysis, and application that would be "engineered" into clinical and business operations.

"We strongly believe that adding on existing tools onto already overloaded workloads becomes prohibitive," in terms of labor and costs, says Zachary J. Meyer, Vice President of MCC's Quality Management Systems. "We have operationally integrated the collection of structured, standardized data elements into a typical clinical assessment."

CQIS is an ongoing improvement system, in which users can use feedback to improve patient care. "We are able to ask questions of the database at any time to see how we have been doing, and then to develop improved treatment protocols," says Elizabeth Opland, a senior clinical quality analyst with MCC.

In 1992, MCC partnered with the Institute for Health Services Research at the University of Minnesota, which already had extensive experience with clinical outcomes research under Robert L. Kane. In 1993, MCC Behavioral Care made its three-volume clinical standards reference guides available to health care, social service, and counseling professionals.

MCC perceives its data as being very "actionable," Opland says. For example, MCC data show that people who have financial or logistical barriers to attending treatment, like babysitting or transportation problems, or co-payments over $20, are only half as likely to engage in treatment. "Now providers are developing solutions, such as offering transportation assistance or extending clinical hours or waiving co-payments," Opland says. "One of our sites in Richmond [Virginia] has started such process improvements. They decided to reduce the co-pay to $5 for the first phase of treatment for substance abuse patients. This gets them involved in treatment, and at that point, other factors start taking primary importance about a successful outcome." MCC is now beginning to pilot combined mental health-substance abuse forms in its 65 offices. Likewise, MCC is piloting the substance abuse forms for MCC's high-volume external providers (outside of MCC offices), who see at least 50 patients per year.

The process for both the mental health and substance abuse modules includes several steps:

▲ Initial assessment—baseline information is gathered from a patient questionnaire. Data are used for the outcomes assessment process and also for clinical care plans, regulatory requirements, and other purposes.
Treatment data collection—once treatment begins, MCC gathers data about type and intensity of treatment, provider characteristics, insurance eligibility and benefits, appointment scheduling, claims, authorization, and encounters.

Follow-up interviews—during six- and 12-month interviews after treatment, patient functioning is evaluated again. Using nine outcome domains, the patient's function is detailed and adjusted for case mix.

The difference in patient function before and after treatment is the measure that illuminates patient outcomes and treatment effectiveness. The CQIS system also allows more than just treatment efficacy to be evaluated. MCC can also determine which form of treatment and which health care provider work best for which kind of patient. MCC uses that specific information to drive quality improvement in practice protocols and delivery systems.

Pigg notes that mental health is a natural area in which to involve pharmacy, because "one of the largest drug expenditure areas is antidepressants, including Prozac." Many other organizations have arisen to determine treatment outcomes for substance abuse and mental health, including Philadelphia-based Deltametrics-TRI, which is devoted to such studies.

**PHARMACIST INVOLVEMENT GETS RECOGNITION**

Lash notes that pharmacists have a valuable role to play in health care quality initiatives both because of their direct contact with patients, in many cases, and because of their access to powerful information systems that yield easily-assessed measures of quality. Pharmacists are finding more opportunities to help develop and launch valuable QI programs, in this era of outcomes and quality measurement.

As a final example, staff pharmacists in Kaiser Permanente's Northwest Region helped to establish a smoking cessation program that involved pharmacists closely in its operation. Pharmacists worked closely with patients, the health educator who instructs patients, and the prescribing physician. Pharmacists prescribed and monitored nicotine therapy replacement therapy by protocol, and monitored each patient for dose-response effect, adverse drug reactions, drug interactions, and progress and outcome. In one year, more than 80 courses were held with nearly 1,000 participants, and rates of long-term abstinence achieved compared favorably with literature rates for community-based group smoking cessation programs. Based on surveys, satisfaction of patients, pharmacists, and physicians, this three-year-old program has been rated as high.

The program serves as an example of how pharmacist expertise can be used to the fullest extent to improve patient health while keeping down costs to the health care system and society at large. By better managing and monitoring therapy, patient education, and patient behavior, pharmacists are proving themselves invaluable as leaders and members of quality improvement programs nationwide.

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**References**


Although cancer is a very grown-up disease, thousands of children like Adam learn all about it each year when they're diagnosed with one of its deadly forms.

But these children have a fighting chance because of life-saving research and treatments developed at St. Jude Children's Research Hospital. To learn more about the work doctors and scientists are doing at St. Jude and how you can help, call:

1-800-877-5833.

**ST. JUDE CHILDREN'S RESEARCH HOSPITAL**

Danny Thomas, Founder
Blue Cross and Blue Shield: Making Pharmaceutical Care a Key Component of Managed Care

For decades, Blue Cross and Blue Shield plans have worked to improve the lives of the millions of patients they serve. Today, advances in pharmaceutical care management are further advancing that goal.

Blue Cross and Blue Shield Plans have long been regarded as the mainstay of the American health insurance system, and for good reason. Roughly 25% of the U.S. population, or more than 65 million lives, receive their health care coverage through 66 independent Blues’ plans nationwide, most of which still operate on a not-for-profit basis. For many Americans, Blue Cross and Blue Shield remains the health insurance plan of choice—as it had been with preceding generations. For these individuals, the Blue Cross and Blue Shield emblems represent more than just corporate logos; they evoke broader personal notions of security, comfort, and trust in the health care system.

As managed care has grown to assume a larger role in the health care delivery system, the Blues have made great strides to keep up. Today, more than 29 million individuals—roughly 45% of all BCBS subscribers and almost 10% of the U.S. population—are enrolled in BCBS managed care networks.
To better meet the health care needs of their large and diverse managed care patient base, many individual Blues plans have implemented and expanded upon their managed care pharmacy programs. In this article, we'll look at two Blues' programs: Pharmacy Gold, the PBM subsidiary of Blue Cross and Blue Shield of Minnesota that serves 16 million lives nationally, and the Federal Employees Program, which provides pharmaceutical care to some 3.5 million Blues-covered federal employees, retirees, and dependents.

PHARMACY GOLD: FROM FORMULARY/REBATE PROGRAM TO FULL SERVICE PBM

Developing a formulary and securing manufacturer rebates on prescription drugs for plan members seemed like a novel idea back in the mid-eighties. But that is what Blue Cross and Blue Shield of Minnesota, Minneapolis, started doing in 1986 and 1987.

"It was done to meet the competition in the market," recalls Richard Bruzek, Pharm.D., vice president of health plan marketing for Pharmacy Gold. Back then, BCBS of Minnesota had about 200,000 managed care enrollees, a sizable number, but no where near the 950,000 HMO and PPO enrollees the plan serves today, Bruzek notes. As the plan's enrollment mushroomed over the years, so did the scope of BCBS of Minnesota's managed care pharmacy program: What began as a formulary and rebate program for the plan's HMO members has evolved into a full-service pharmacy benefits management company serving HMOs and other PBMs nationally, as well as Minneapolis-based employers.

BCBSM's pharmacy program had its origins in the desire to provide better quality care for HMO patients, not just reduce costs. In 1986, BCBSM developed a drug formulary for its members based on the clinical recommendations of an expert panel of physicians and pharmacists that is still in place today.

Once the list of approved drugs was in place, the plan began seeking discounts on the chosen drugs from manufacturers. That was no easy task initially. "It was difficult to secure [prescription] discounts [from manufacturers], because managed care was so new," Bruzek says. Most rebates, he notes, were not that substantial during the program's early years. But even the small discounts soon started translating into big savings, given that the plan dispensed roughly 6 million prescriptions a year. Over time, those rebates grew.

BCBSM soon recognized that Blues plans elsewhere also would benefit from a formulary and drug rebate program. So in 1989, BCBSM created Pharmacy Gold. The following year, several Blues plans signed up with the program, which in addition to offering rebates on prescription drugs, also offered plans the option of using the BCBSM formulary or having a customized formulary made to "meet local community prescribing needs and patterns."

The idea caught on. Between 1990 and 1992, the number of lives covered under Pharmacy Gold grew from 2 million to 4 million—and by 1993, the number surged to 10 million. That same year, the company decided it would market to non-Blues-affiliated groups, including HMOs, PPOs, and PBMs. But to do that effectively, Pharmacy Gold would have to offer more than just rebates and formularies.

Today, Pharmacy Gold is a full PBM provider, serving more than 16 million lives nationwide and offering a broad array of services ranging from formulary development and network management to more sophisticated DUR and claims processing programs. Some features of Pharmacy Gold's program include:

- A national network of more than 35,000 pharmacies that provide discount services and broad access. An automated directory allows consumers to call a toll-free number 24 hours a day to locate the nearest pharmacy.
- Prospective, concurrent, and retrospective DUR.
- Discount mail order prescription services providing 24-hour access to clinical pharmacists can answer questions about medication and consult with physicians.
- Gold Link, an automated system that allows clients direct access to their utilization data via computers.

Being able to customize pharmacy programs to meet clients' needs is perhaps one reason why Pharmacy Gold has seen dramatic growth in recent years. For example, Pharmacy Gold now offers clients specialty formularies for workers' compensation, injectables or home infusion therapy, nonprescription drugs, and therapeutic indices/disease management.

Use of medical guidelines also has become an integral part of Pharmacy Gold's program, according to Bruzek. Physicians and other health care professionals who prescribe medications can access the guidelines for 13 therapeutic categories, so they know in advance specifically which positive outcomes patients should experience under their treatment regimens. For example, asthma patients prescribed a particular medication or given some other treatment might be expected to experience fewer nocturnal awakenings. Pharmacy Gold is gearing up to allow providers on-line access to the guidelines, so they can reference them when working with the patient. Using this so-called interactive therapeutic matrix, a physician treating a hypertensive patient can instantly access information about specific treatment regimens for that disease.

In 1995, Pharmacy Gold combined its formulary with the guidelines and distributed them to physicians. "We've gotten lots of feedback from physicians," much of it positive, Bruzek says. Some providers have requested additional copies of the document, or have sought additional information about what was provided, he says.

Another new feature of Pharmacy Gold's program is Prime Therapeutics, which relies on provider and consumer educational outreach, targeted DUR and case management initiatives to improve patient care and reduce per member per month costs. "For too long, PBMs have concentrated too much on [manufactur-
er] discounts and administrative fees rather than on drug ingredient costs," he says. "So this is really a new direction for us." Prime Therapeutics will allow Pharmacy Gold to help clients select the best formulary drug therapies for certain therapeutic categories based on pharmacoeconomic and medical outcomes research and evaluation.

"We can't think of pharmacy costs in isolation from medical costs," says Bruzek, who adds that the plan is working to better link medical data with pharmacy data so care givers can better track patient outcomes on certain drug therapies versus others.

THE BLUES' FEDERAL EMPLOYEE PLAN: A PARTNERSHIP WITH THE PATIENT IN MIND

The Federal Employees Health Benefits Program (FEHBP) is the largest privately insured health benefits program in the world, providing health coverage to roughly 9 million federal workers, retirees, and dependents nationally. More than 300 separate health plans and carriers participated in the mammoth federal program in 1995, and, as in past years, the Blues covered the largest bulk of those individuals—roughly 3.5 million members. About 44% of all covered federal workers and retirees enroll with the Blue Cross Blue Shield Service Benefit Plan, also known as the Federal Employees Program (FEP). Under FEP, the Blue Cross Blue Shield Association contracts with the federal government on behalf of the nation's 66 independent Blue plans.

Prescription drugs have always been a key component of the FEP program. During the mid-1980s, prescription coverage, once offered as a supplemental benefit, was revamped and included under the major medical component of the plan. But increasing competitive pressures prompted FEP to look for ways to offer better value to consumers. So in 1987, FEP introduced its optional mail service prescription drug program for enrollees on maintenance or long-term drug therapy.

The program, administered by National Rx Services, Inc., a division of Medco Containment Services, offered subscribers several new advantages, including no annual deductible and no claims to file, says Keven Thompson, FEP's Program Manager for Pharmacy Policy. Also, subscribers pay only a small, flat copayment for each prescription filled, she adds.

Medco's mail service program also offered FEP advantages that could in turn be passed on to consumers. These included better drug-utilization review techniques—including on-line editing of drug therapy—and data management to enhance patient quality of care, Thompson says. It also reduced drug costs by securing manufacturer rebates and discounts off the average wholesale price for drugs.

Despite these efforts, drug utilization and costs continued to spiral at FEP, jumping from 8% of total benefits paid in 1985 to 18% in 1991, and growing at a rate of 18% a year. Those did not even account for the additional medical costs related to illnesses patients incurred because of drug overuse, adverse drug interactions, or other inappropriate prescribing situations.

FEP realized the only way to get a better handle on drug use, quality of care, and costs would be to extend some of the same features already built into the mail order component to the retail portion of the program—where the vast bulk of prescriptions were being filled. So in 1993, FEP implemented a new retail pharmacy program administered by PCS Health Systems, Inc. Under this system, FEP members can access a broad network of preferred pharmacies that offer discounts, medication counseling, and DUR. Today, more than 43,000 retail pharmacies nationally participate in the network. Members present their identification cards to network pharmacies at the time they fill their prescriptions, and no longer have to file claims.

Although the mail order and retail drug programs are operated separately by two competing vendors, there is room for collaboration, Thompson says. PCS and Medco, she adds, work as a team "to coordinate safe and effective drug treatment regimens." The two vendors swap patient drug utilization data on a daily basis. "If a patient orders a prescription through the mail, then tries to obtain the same drug through a retail outlet, we can track that," she says.

Through the Medco mail order program, FEP has for several years been able to perform concurrent drug utilization review at the point of sale. The DUR program alerts pharmacists of the potential for medication complications, such as when a patient may have a drug interaction, be receiving duplicate therapies, or be taking an unusually high daily dose, says Joyce Durcanin-Robins, Associate Director of Clinical Services at Medco Containment Services, Inc. With the addition of the PCS program, FEP can now also track and monitor patient use profiles at the retail level, giving dispensing pharmacists and FEP prescription drug benefits administrators new tools for identifying and preventing potential problems stemming from inappropriate drug use and prescribing. That in turn is improving quality of patient care—and reducing unnecessary utilization and costs.

For example, FEP can now perform drug-use review to keep closer watch on high-risk retail-user patients who experience so-called "medication misadventures," such as being on several controlled substances at one time, says Jean Brown, Director of Clinical Services with PCS Health Systems. FEP reviews the patient's profile, identifies the prescribing physician or physicians, and notifies the doctors of the problem in writing. Of those physicians who respond back, "70% are positive," Brown says. Many "didn't even know that their patients were seeing other doctors for the same problem." The strategy seems to be working: Within a year of the program's implementation, "we saw an 8.5% change in prescribing activity," Brown says.

In 1995, FEP began working with PCS further to try to determine whether prescribing patterns at the retail level...
were linked to patterns in medical treatment. "We identified one elderly hypertensive patient who was on several antihypertensive medications at once," Brown says. Medical records showed that the patient, a woman, had been seeing three different physicians for the same problem, although none of the doctors knew the patient had been seeking care for her condition at other providers. Claims data also showed that the patient had been admitted to the hospital several times during the course of the year for assorted problems including fainting spells, mental confusion, and a broken hip from a fall. FEP drug benefit administrators suspected that these medical problems may have been caused by the interactions of the three antihypertensive medication drugs that patient was taking simultaneously.

FEP notified the patient's treating physicians of the situation in writing. The result: the physicians have agreed to refer the patient to one attending physician, a cardiovascular specialist, for all outpatient care. A recent look at the patient's medical and prescription drug records show that she now is making fewer hospital and doctor visits, "and she's complying with her medication," Brown says.

Such interventions on a patient's behalf are "very time intensive," says Brown, who adds FEP is in the process of automating its system so all medical and prescription data will be in each patient's profile. This way, physicians can see the patient's recent medical and prescribing history right on his or her computer screen at the time of treatment. That should prevent medication mishaps from occurring in the first place and reduce the need for outside intervention by the program.

Both Medco and PCS continue to work with FEP to further improve the level of pharmaceutical care provided.

Some examples of new FEP program features include the following: 

▲ Prior Approval Drug program, introduced in 1994, to determine coverage for select prescription drugs that are used by patients to treat covered as well as non-covered conditions or illnesses. Under the FEP program, for example, the drug Retin-A is covered when used to treat severe acne, but not when used for other cosmetic purposes, such as reducing age-related skin wrinkles. Patients needing drugs on the prior approval list will need to get special authorization from their physicians before the prescription is filled.

▲ Excessive treatment duration edits, introduced in 1995, to monitor extended therapy with selected agents. For example, H2 antagonists for ulcer treatment should generally be taken for acute conditions, not for prolonged periods, Thompson says. Prolonged use may indicate that the patient is not being prescribed other agents that may be more effective in treating the disease at an advanced stage, such as antibiotics.

▲ Evaluation of the use of denial, rather than alert messages, for selected adverse drug interactions. Under the program launched last year, pharmacists receive STOP messages or denials from the computer whenever they are about to dispense a drug likely to cause a potentially severe adverse reaction. Pharmacists are then required to contact the patient's physician before dispensing the medication. One pilot program now underway is trying to determine to what extent pharmacists who are well-informed about potential adverse reactions heed alert messages and change their dispensing behavior as a result.

▲ Introduction of Medco's Diabetic Patient Support Program. More than 16,000 FEP patients are now enrolled in this program, which pays careful attention to the special needs of this population. FEP and Medco are collaborating on a health care utilization analysis involving medical and pharmacy claims data to determine whether the program has been successful in improving the lives of diabetic patients.

In 1996, FEP will initiate a number of additional pharmaceutical care quality improvement programs. Some examples include:

▲ Expanded quality assurance program to make sure that patients are not misusing their prescription drugs. For example, prolonged or heavy use of certain types of pain killers may indicate a patient has become addicted to the drug. FEP recently intervened in a case where a patient was found to have used more than 1,000 vials of a particular pain-killing agent within a year's time. The prescribing physician who was later contacted by the plan about the situation had no idea that the agent he was prescribing had addictive properties, Thompson says.

▲ Launch Medco's Partners for Healthy Aging Program, a fully integrated mix of innovative drug management services tailored to meet the unique needs of the elderly. The product includes senior-focused prescribing guidelines, clinical edits, and DUR interventions as well as comprehensive patient profiles and educational tools, Durcanin-Robbins says. This program is believed to be the first and only pharmaceutical management program to measurably reduce seniors' health care costs and improve quality of care, she adds.

FEP also is moving ahead in the fast-growing disease management area by implementing several pilot projects on a plan-by-plan basis. FEP initially will target respiratory and digestive system diseases, which now account for a large proportion of the plan's annual medical and drug claim payouts—about $750 million. FEP will assess the results of the programs within a 12- to 24-month period and evaluate the potential for their use systemwide. Meanwhile, PCS is conducting a pharmacy-specific analysis of intervention/outcome data to provide an additional tool for measuring pharmacy effectiveness and further support PCS' concurrent DUR program.

The rapid pace with which the Blues have adopted sophisticated pharmacy management and pharmaceutical care techniques suggests there will be many more innovations and challenges in the years to come. Like other key managed care players, the Blues are moving full force to embrace these changes to ensure that the millions of patients they serve continue to trust the Blue Cross Blue Shield name.
Drug-Related Morbidity and Mortality: A Cost-of-Illness Model

Jeffrey A. Johnson
Lyle Bootman

BACKGROUND:
Preventable drug-related morbidity and mortality represent a serious medical problem that urgently requires expert attention. The costs to society of the misuse of prescription medications, in terms of morbidity, mortality, and treatment, can be immense. To date, research has primarily documented increased rates of hospitalization secondary to medication noncompliance and/or adverse drug effects.

OBJECTIVES:
To develop a conceptual model of drug-related morbidity and mortality, and to estimate the associated costs in the ambulatory setting in the United States.

METHODS:
A probability pathway model was developed to estimate the cost of drug-related morbidity and mortality in the United States. Pharmacist practitioners were surveyed to determine conditional probabilities of therapeutic outcomes owing to drug therapy. Health care use and associated costs owing to negative therapeutic outcomes were estimated.

RESULTS:
Drug-related morbidity and mortality was estimated to cost $76.6 billion in the ambulatory setting in the United States. The largest component of this total cost was associated with drug-related hospitalizations.

When assumptions of the model were varied, the estimated cost ranged from a conservative estimate of $30.1 billion to $136.8 billion in a worst-case scenario.

CONCLUSIONS:
The cost of drug-related morbidity and mortality in the ambulatory setting in the United States is considerable and should be considered in health policy decisions with regard to pharmaceutical benefits. Policies and services should be developed to reduce and prevent drug-related morbidity and mortality.

J Managed Care Pharm 1996: 2: 39-47.

When medications are prescribed for patients for the treatment of disease, the full intent of all parties involved should be the achievement of an optimal therapeutic outcome. Optimal therapeutic outcome has been defined as an absence of drug-related problems (DRPs). When a DRP is defined as an event or circumstance that involves a patient's drug treatment that actually, or potentially, interferes with the achievement of an optimal outcome. Eight general categories of DRPs have been identified (Table 1).

Unresolved or unrecognized DRPs may manifest as drug-related morbidity, which has been described as the phenomenon of therapeutic malfunction or miscarriage—the failure of a therapeutic agent to produce the intended outcome. If left untreated, drug-related morbidity may ultimately lead to drug-related mortality. While it is recognized that some drug-related morbidity and mortality is owing to patient idiosyncrasy, and therefore unavoidable, there is a considerable body of literature that suggests that a large proportion of drug-related morbidity is preventable.

Manasse used the term "drug misadventuring" to describe these inappropriate outcomes, and he proposed that the problem must be viewed as one of public policy. Manasse suggested that the costs to society of the misuse of prescription medications, in terms of morbidity, mortality, and treatment, can be immense. He also suggested that the new policy decisions must be constructed in the best interest of the patient. The extent and cost of drug-related morbidity and mortality are of great importance to health care practitioners, administrators, patients, and society as a whole.

Estimates of personal health expenditures for prescription medications in 1994 have exceeded $73 billion. Recent literature has indicated that the substantial costs associated with inappropriate drug-use behavior may even exceed these initial expenditures for drug therapy.

To
Untreated
Overdosage
Problem
Date,
additional
impact
of
these
direct
indirect
hospitalizations
during
outpatient
medical
drug
reactions
Interactions
reaction.
interactions
Drug-use without indication

<table>
<thead>
<tr>
<th>Problem</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untreated indication</td>
<td>The patient has a medical problem that requires drug therapy but is not receiving a drug for that indication.</td>
</tr>
<tr>
<td>Improper drug selection</td>
<td>The patient has a drug indication but is taking the wrong drug.</td>
</tr>
<tr>
<td>Subtherapeutic dosage</td>
<td>The patient has a medical problem that is being treated with too little of the correct drug.</td>
</tr>
<tr>
<td>Failure to receive drugs</td>
<td>The patient has a medical problem that is the result of not receiving a drug (e.g., for pharmaceutical, psychological, sociological, or economic reasons).</td>
</tr>
<tr>
<td>Overdosage</td>
<td>The patient has a medical problem that is being treated with too much of the correct drug (i.e., toxicity).</td>
</tr>
<tr>
<td>Adverse drug reactions</td>
<td>The patient has a medical problem that is the result of an adverse drug reaction or adverse effect.</td>
</tr>
<tr>
<td>Drug interactions</td>
<td>The patient has a medical problem that is the result of a drug–drug, drug–food, or drug–laboratory interaction.</td>
</tr>
<tr>
<td>Drug-use without indication</td>
<td>The patient is taking a drug for no medically valid indication.</td>
</tr>
</tbody>
</table>

Data from Hepler and Strand and from Strand et al.

Date, research has primarily documented increased rates of hospitalization secondary to medication noncompliance and/or adverse drug effects. Sullivan et al. estimated the direct medical costs associated with hospitalizations owing to medication noncompliance to be $8.5 billion. The authors suggested that an additional $17–24 billion would be incurred as indirect costs. A more recent estimate has put the direct costs of noncompliance at greater than $50 billion, with an additional $50 billion in indirect costs.

While noncompliance and resultant hospitalizations are certain to account for a large proportion of DRPs and associated direct medical costs, respectively, limiting an analysis to these issues alone would surely underestimate the true extent of drug-related morbidity and mortality. Likewise, direct costs of hospitalizations would also underestimate the economic impact of the “illness,” as only the direct costs associated with those misadventures of sufficient severity to warrant hospital admission would be captured. What of the costs associated with outpatient visits? Or of return visits to the pharmacy? Or additional treatment of any new medical problems? An analysis of the direct costs of illness of drug-related morbidity and mortality should take into consideration these aspects of management of the “disease.” To date, there have been no reports, of which we are aware, of the total economic impact of such drug misadventuring, and further analysis is warranted.

Recent debates in the health and public policy arena have considered the impact of a pharmaceutical benefits plan that would include coverage of products and services. The DRPs and drug misadventuring should be considered in these policy issues. An estimate of the costs associated with drug-related morbidity and mortality will aid in the policy-making decisions area. In an attempt to address this issue, the present investigation was undertaken. Two objectives were set: (1) to develop a conceptual model of therapeutic outcomes that may result from drug therapy; and (2) to estimate the magnitude of the cost of drug-related morbidity and mortality in the United States.

(See pages 43-45 for Methods.)

ESTIMATES OF THERAPEUTIC OUTCOMES

According to the panel members, 23.4 ± 13.2% (mean ± SD) of patients who receive drug therapy would experience a TF owing to DRPs; 10.5 ± 5.4% would experience an NMP, and 6.5 ± 4.1% would experience a combination of a TF and an NMP. The panel members estimated that less than 60% of patients who were receiving medication would have an absence of DRPs (i.e., an optimal outcome).

Estimations of the health care resources that would be used in the management of negative therapeutic outcomes differed for the three possible outcomes. Panel members estimated that approximately 8–18% of negative therapeutic outcomes would not require further attention of a health care professional, but 15–23% of patients would see a physician, and 42–49% would require further prescription medication. Negative therapeutic outcomes would lead to an urgent care visit or emergency department visit for 12–19% and 6–12% of patients, respectively. Four panel members did not provide a response to the urgent care visit item, as this was a service that was unfamiliar to those panel members in their practice setting. Because of these missing data, the urgent care visit outcomes were collapsed into physician visits such that the probabilities could be inserted into the decision analysis model.

The panel also estimated that 5% of patients who experience a TF or in whom an NMP would develop would be admitted to a hospital; a combination of negative therapeutic outcomes would lead to a higher percentage of patients being admitted to a hospital, that is, approximately 9%. Most panel members estimated that less than 1% of negative therapeutic outcomes would result in an admission to a long-term care facility. Death was estimated to occur in less than 1% of patients who were receiving medications.

COST OF DRUG-RELATED MORBIDITY AND MORTALITY

Folding back the decision tree, to merge the conditional probabilities and costs of all pathway outcomes, produced the mean aggregate cost that was associated with health care encounters. The expected cost of a physician visit was $194
Table 2. Drug-Related Morbidity and Mortality Cost Definitionsa

<table>
<thead>
<tr>
<th>Pathway outcome</th>
<th>Initial treatment ($)</th>
<th>Cost of negative therapeutic outcome ($)</th>
<th>Total Pathway Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician visit</td>
<td>Drug</td>
<td>Physician Visit</td>
<td>Drug</td>
</tr>
<tr>
<td>64.50</td>
<td>25.32</td>
<td>64.50</td>
<td>64.50</td>
</tr>
</tbody>
</table>

a ED indicates emergency department; LTC, long-term care; TF, treatment failure; and NMP, new medical problem.
b Estimated drug cost for TF and TF/NMP are reduced by 10% to reflect rate of new prescriptions never filled.

Table 3. Health Care Utilization and Cost for Drug-Related Morbidity and Mortality in the United Statesa

<table>
<thead>
<tr>
<th>No. of events</th>
<th>Cost ($) (in thousands)b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician visits</td>
<td>115,654,949</td>
</tr>
<tr>
<td>Additional prescriptions</td>
<td>76,347,604</td>
</tr>
<tr>
<td>ED visits</td>
<td>17,053,602</td>
</tr>
<tr>
<td>Hospital admissions</td>
<td>8,761,861</td>
</tr>
<tr>
<td>LTC admissions</td>
<td>3,149,675</td>
</tr>
<tr>
<td>Deaths</td>
<td>193,815</td>
</tr>
<tr>
<td>Total</td>
<td>76,557,711</td>
</tr>
</tbody>
</table>

a ED indicates emergency department; LTC, long-term care.
b Costs may not total correctly because of rounding off.

(95% confidence interval, $154 to $234). This cost figure has no intrinsic value, but is simply the weighted mean cost of the entire pathway model (i.e., all possible outcomes).

When therapeutic outcomes owing to drug therapy were modeled for the ambulatory population of the United States, the estimated cost that was associated with the management of drug-related morbidity and mortality was $76.6 billion, annually (Table 3). The largest component of the total cost comprised drug-related hospitalizations, that is, an estimated 8.76 million admissions at a cost of $47.4 billion, annually, or approximately 62% of the total cost. Based on 31.1 million hospital admissions in 1992,19 the number of admissions that was estimated from the model suggested that 28.2% of all hospital admissions were a result of drug-related morbidity and mortality.

Admissions to long-term care facilities represented the second largest component of the total cost of illness, with 3.15 million admissions at a cost of $14.4 billion (Table 3). Visits to the physician resulting from DPRs would exceed 115 million, and these visits would cost nearly $7.5 billion, while an additional 76.3 million prescriptions were required to resolve TFs and NMPs, adding $1.93 billion to the cost. This represents 17.3% of all physician office visits,24 and 8.2% of all prescriptions6 that were estimated for 1992. The number of emergency department visits that resulted from drug-related morbidity represented 18.9% of an estimated 89.8 million emergency department visits in 1992.26

SENSITIVITY ANALYSES

When the probabilities of negative therapeutic outcomes were varied throughout the range provided by the panel, the costs that were associated with drug-related morbidity and mortality ranged from $30.1 billion for the more conservative end of the range of negative therapeutic outcomes to $136.8 billion in a worst-case scenario. When the assumed rate of initial noncompliance was increased to 25%, the estimated cost
that was associated with DRPs increased to $128.2 billion.

The analysis was sensitive to the cost assumptions that were included in the model, particularly for costs of hospital and long-term care admissions. A cost of treatment of $37.9 billion was estimated when the cost of hospitalization was reduced to $1,000 per admission; the figure increased to $204.3 billion when a cost of $20,000 per admission was used. The hospital costs that were chosen for this sensitivity analysis were an arbitrary range.

The cost of a long-term care admission in the base-case analysis was based on the reported median length of stay of 82 days. When an average length of stay (401 days) was used, the estimated cost of a long-term care admission was $22,355. The inclusion of this figure in the model produced a cost of illness of $132.6 billion.

COMMENT

Causes of preventable drug-related morbidity and mortality may be a result of inappropriate behavior, be it noncompliance by the patient, or inappropriate prescribing and/or monitoring by health care professionals. As such, drug-related morbidity and mortality could be considered a "behavioral disease." With this view, an estimate of the economic impact of the "disease" could be assessed by using cost-of-illness methods. Analyses to assess the economic impact of illnesses on society have been performed since the mid-1960s; with most of the major medical conditions being assessed at one time or another. While some economists believe that cost-of-illness studies provide little information with regard to resource allocation decisions, one important role for these analyses is as a baseline assessment, against which new programs or policies can be evaluated.

The cost of illness associated with DRPs estimated in this analysis would serve to strengthen the suggestion of Manasse that drug-related morbidity and mortality is a serious medical problem and should be considered an issue of public policy. The analysis presents a figure that can now be debated, but it is clear that the problem is more than a minor concern for the health of the nation.

To put the results of this analysis in perspective, the cost-of-illness figures could be compared with the estimated costs of other conditions in the United States (Table 4). For example, obesity was estimated to cost $45.8 billion in direct costs in 1990. All diabetes care has been estimated to cost $45.2 billion, annually. Non-insulin-dependent diabetes mellitus care cost $15.5 billion in 1990. The treatment of cardiovascular disease have been estimated to cost $117-$154 billion. Our results indicate that drug-related morbidity and mortality should be considered one of the leading disease in terms of resources consumed.

As stated earlier, the cost estimations made in this analysis were limited to the direct costs of managing drug-related morbidity and mortality. A more complete estimation (i.e., a societal perspective) of the costs associated with this health condition is beyond the scope of this analysis.
METHODS:
CONCEPTUAL MODEL FOR DRUG-RELATED MORBIDITY AND MORTALITY

A probability pathway model for drug-related morbidity and mortality was developed (Figure) that was based primarily on the DRPs and negative therapeutic outcomes as described in recent literature.\(^1\) Any one, or a combination, of these DRPs may occur in any given patient, and may lead to treatment failures (TFs) and new medical problems (NMPs) as possible negative outcomes. An absence of DRPs would represent the optimal therapeutic outcome. These outcomes were used as the basis for the conceptual model. However, because a TF and an NMP may occur in the same patient as a result of a number of DRPs, a third negative therapeutic outcome was included (i.e., a combination of a TF and an NMP) to make the possible therapeutic outcomes mutually exclusive. An example of a TF due to a DRP would be an unresolved infection following improper antibiotic selection; an NMP might be a rash that develops after starting antibiotic therapy. A combination of negative therapeutic outcomes might occur when an infection is treated with an improper antibiotic, which causes a rash.

For patients experiencing a TF or an NMP due to DRPs, it was thought that one of eight subsequent events could occur as follows: (1) a revisit with a physician, (2) a further prescription medication, (3) an urgent care visit, (4) an emergency department visit, (5) a hospital admission, (6) a long-term care facility admission, (7) death, or (8) no further attention of a health care professional. These eight events were defined as the end points, or final resolutions, of negative therapeutic outcomes, as such, to be mutually exclusive (i.e., their respective probabilities would sum to 1.0). For example, with regard to event 2, a further prescription medication implies a preceding physician visit, so that event 1 then represents patients who revisited a physician but had no further treatment.

While the morbidity and mortality and associated costs, resulting from the use and abuse of illicit drugs, are recognized as a substantial problem, an attempt to assess the economic impact of such behavior was considered to be beyond the scope of this project. It should also be noted that DRPs and associated costs were estimated for ambulatory settings and, such, did not include those that may occur in institutional settings (e.g., hospitals, long-term care facilities).

To determine estimates of the probabilities of negative outcomes of drug therapy, a panel of pharmacists was surveyed. These individuals were selected based on their extensive clinical practice in an ambulatory setting and recognition as leaders in pharmacy practice in the United States. The primary goals of each of their clinical practices were the identification, resolution, and prevention of DRPs. A letter of invitation was sent to 18 potential panel members; this letter explained the objectives of the project. Invitation letters were followed by a telephone call to confirm panel participation and to schedule a 30-minute telephone interview. Telephone problem would include some consideration of the indirect costs, that is, the economic impact of lost productivity as a result of morbidity and mortality.\(^27\)\(^-\)\(^28\) Rice et al.\(^30\) indicated that, overall, the indirect cost of illnesses exceed the direct costs. Sullivan et al.\(^8\) suggested that the indirect costs associated with medication noncompliance was an additional $17–$25 billion, that is, two to three times the estimated direct costs. Applying this ratio to the estimates calculated in the present analysis would suggest that the total cost of all preventable drug-related morbidity and mortality to the United States, in terms of health care costs as well as lost productivity, would amount to $138–$182 billion.

The limitations to the estimates made from the model should be obvious. The model developed for this project was conceptual, and the probabilities attached to therapeutic outcomes, as well as the cost figures assigned to the outcomes, were estimations. As such, the cost of illness is only an estimate. However, the sensitivity of the model to the panel's estimations was extensively tested through sensitivity analysis, and the cost definitions used in the model were transparent.

Of primary concern to many readers will be the appropriateness of the chosen panel members. The panel members were composed of expert practicing pharmacists, with no representatives from the physician or nursing community. As such, the estimations made by the panel members may be viewed by some as biased. A panel member composed of other health care professionals might help to reduce potential bias. However, the difficulty then lies in the identification of such a panel member; for example, should physicians be general practitioners, specialists, or clinical pharmacologists? In addition, the practitioners included in the panel were trained specifically to identify, prevent, and resolve DRPs, whereas other health care professions do not have the same focus.

If the probabilities of therapeutic outcomes estimated by the expert panel are accepted as "best estimates," and the monetary values assigned to outcomes are also considered appropriate, then it may be the model within which these figures were used that may be questioned. Was it the correct model? Were important outcomes not included? These questions are more difficult to address.

 Appropriateness of the model may be judged by comparing the results of this analysis with findings from previous reports of drug-related morbidity and mortality. Our estimates appear to be in line with those of other reports. The estimated number of deaths owing to DRPs in this analysis ranged from 79,159 to 198,815 deaths. Tally and Laventurier\(^2\) estimated that 140,000 patients died in the United States because of adverse drug reactions in 1971.

Several studies have attempted to quantify the rate of drug-related hospital admissions. Reported rates have ranged
All panel members were currently practicing; advanced pharmacy degrees were held by nine panel members (Pharm.D. \( n = 6 \), M.Sc. \( n = 2 \), and Ph.D. \( n = 1 \)). Three panel members had advanced degrees in public health (M.P.H. \( n = 2 \) and Dr.P.H. \( n = 1 \)). Most panel members (nine of 15) indicated that their primary practice setting was ambulatory; four panel members characterized their practice setting as part of a managed care organization, and two indicated long-term care as their primary setting.

A standardized interview form was developed based on the cost-of-illness model described above. Respondents were instructed to provide their estimate of the likelihood of the three negative therapeutic outcomes owing to drug therapy in patients in a typical ambulatory health care setting in which they were not available to provide their current level of clinical practice. Respondents were then asked to estimate the percentage of patients who experienced each of the three negative therapeutic outcomes that would require further attention and utilization of additional health care resources. All items were open-ended questions. To facilitate the scheduled telephone interviews, the interview form was faxed to all participating panel members approximately four to five days before their scheduled interviews. Respondents were also provided with a schematic diagram of the pathway model (Figure 1).

Meta-analysis, performed by Sullivan et al., resulted in a weighted estimate of 5.3% of hospitalizations being due to noncompliance. More recently, Einarson reported the results of a meta-analysis of studies that dealt with hospitalizations due to reactions that occurred while the patient was taking medications appropriately or to reactions that resulted from noncompliance or unintentionally inappropriate drug use. The analysis indicated that a weighted rate of 5.1% of hospital admissions were owing to these causes.

According to the model in the present analysis, the number of drug-related hospital admissions ranged from 3.5–8.8 million annually, representing 11.3–28.2% of estimated hospital admissions in 1992. These estimates appear to be higher than those in previous reports. However, those previous estimates were focused on hospital admissions that resulted from noncompliance alone, or as the result of an adverse drug reaction. Because the present estimate included negative therapeutic outcomes owing to all types of DRPs, the estimated number of hospital admissions would be expected to be greater.

In addition, documentation drug-related hospital admissions is difficult, and it is possible that many hospital admissions are the result of DRPs that go unrecognized. For example, a patient with insulin-dependent diabetes who is admitted to a hospital with diabetic ketoacidosis may be more

likely to be classified as a drug-related admission than an asthmatic patient who has underutilized his or her inhaled corticosteroids. As a result, the number of drug-related admissions documented in previous reports may underestimate the problem.

An additional point that should be considered in the evaluation of this model and the cost estimates in the model relates to high-risk groups. Of particular importance are elderly patients who would be considered to be at high risk of DRPs and negative therapeutic outcomes for a number of factors that are unique to that age group, including the physiologic effects of aging on the disposition of drugs, multiple disease processes, and multiple, concurrent drug therapies. The estimations of likelihood of negative therapeutic outcomes made by the expert panel members for this analysis were made for the general ambulatory population. If elderly patients were to be considered alone, the risks would have been greater.

Highlighted by the results of this analysis is the serious nature of all drug therapy. In all estimations, despite the best efforts to achieve optimal therapeutic outcomes by players on the health care team, there remains a considerable expense (and a sizable number of deaths resulting from drug therapy) that might be considered unavoidable. As Manasse indicated, "the reality of introducing a chemical agent into the body is accompanied predictable (and often unpredictable) elements
cial visit, an initial prescription for the offending drug, and then a revisit to the physician. The revisit then may or may not lead to an additional prescription. Alternatively, a new medical problem may require hospitalization for proper treatment, and the associated costs should include not only the cost of the hospital stay but also the cost of the initial physician visit and prescription.

Conditional probabilities for all therapeutic outcomes, based on responses from the panel members, were inserted into the decision analysis model. The expected cost of drug therapy following a health care encounter under each scenario were calculated by “folding back” the decision tree. Folding back is the process of multiplying the cumulative conditional probabilities by the cost of the outcomes, and then summing these values to determine the mean aggregate cost of the scenario.22 The expected cost is not a prediction of what will actually occur but is simply a weighted average of the possible outcomes.23

**COST-OF-ILLNESS ANALYSIS**

Health care utilization and associated costs owing to negative therapeutic outcomes in ambulatory populations were estimated. The number of revisits to physicians, additional prescriptions, long-term care admissions, and deaths owing to negative therapeutic outcomes were calculated by multiply-

of risk” and it is “simply unrealistic to contemplate the ability to take the risk out of risk” with respect to drug development and consumption. However, it is perhaps possible that, given the opportunity to reduce the “preventable” component of drug-related morbidity and mortality, the proportion that is currently considered “unavoidable” may also be reduced.

Preventable drug-related morbidity and mortality represents a serious medical problem that urgently requires expert attention.1,3,4 The extent to which negative therapeutic outcomes can be minimized would represent the value of that expert attention. Given the estimates of the costs associated with DRPs, even a 10% reduction in this inappropriate behavior could lead to substantial savings to the health care system and to society as a whole.

Pharmaceutical care may provide the basis on which health care professionals can make that impact. Pharmaceutical care is a practice philosophy that was put forth by Hepler and Strand1 and embraced by most pharmacy practice organizations.37-39 It is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient’s quality of life.1 The desired outcomes are stated as (1) cure of a disease, (2) elimination or reduction of a patient’s symptoms, (3) arresting or slowing of a disease process, or (4) preventing a disease or symptom. Pharmaceutical care is patient-oriented, and it involves the implementation and monitoring of a therapeutic plan that is designed to achieve these outcomes.1 The presence of DRPs lead to less than optimal therapeutic outcomes. A major function of pharmaceutical care then is to identify, prevent, and resolve DRPs.

While not addressed in this analysis, the effect of drug-related morbidity and mortality on the quality of life of patients might also be considered. The very definition of pharmaceutical care is an intended improvement of a patient’s quality of life, presumably through the cure or arrest of a disease and/or an elimination of symptoms.1 From this, the provision of pharmaceutical care to the ambulatory medical population of the United States would not only lead to a substantial cost avoidance but it might also be expected to lead to an improvement in the general well-being and health status of the population.

The development and refinement of the pharmaceutical care concept represent somewhat of an “awakening” for the profession of pharmacy. While many pharmacists have provided services that constituted pharmaceutical care, the overwhelming sentiment in the pharmacy literature is that pharmaceutical care is being provided by only a relatively small proportion of pharmacists in select practice settings. Primary reasons for this include a lack of education, training, and support, a lack of resources, and a lack of a reimbursement system for those services.40

Pharmaceutical care holds tremendous opportunity for pharmacists to realize their full potential as members of the health care team.1 However, the responsibility of pharmaceutical care of patients cannot be held by a single profession. In-

**SENSITIVITY ANALYSES**

Because the data used in the cost-of-illness model were based on estimations by the panel members, a series of one-way sensitivity analyses22 were performed for plausible ranges in the following variables: (1) the ranges in likelihood of negative therapeutic outcomes indicated by the panel members, (2) all cost estimates included in the model, and (3) estimates of initial noncompliance with prescriptions.

All probability calculations, cost analyses, and sensitivity analyses were performed by using Decision Analysis by TreeAge (DATA)v2.523 and Microsoft EXCEL v4.0 (Microsoft Corp., Redmond, Wash.)
stead, it is perhaps the bridge that is necessary for the interdisciplinary team approach to patient treatment. By definition, pharmaceutical care engenders a multidisciplinary approach to patient treatment. While the literature with regard to pharmaceutical care has been largely contained in the pharmacy community, it cannot truly be provided in isolation of medical and nursing care. The responsible provision of drug therapy involves proper diagnosis, prescribing, and monitoring.

For most drug therapies, diagnosis and prescribing remain the physician’s responsibility; nurses have played, and should continue to play, a vital role in patient monitoring. Based on their training and knowledge base, pharmacists might be expected to provide the bulk of pharmaceutical care, proper diagnosis and prescribing are required to minimize preventable drug-related morbidity and mortality. Pharmaceutical care should be provided to patients in the same way the medical and nursing care are attempts to achieve optimal therapeutic outcomes.

Hepler and Strand indicated that “the empirical bases of pharmaceutical care suggest that there may be a substantial overlap between clinical effectiveness and cost-effectiveness.” However, despite an implicit cost-effectiveness, the costs and benefits of the provision of pharmaceutical care should be made explicit to convince policymakers of the value of enhanced pharmacy services. In times of limited resources allocation, it is necessary to justify the economic outlay demanded by new or enhanced programs. The provision of pharmaceutical care should be no different.

A body of empirical research exists that has demonstrated the benefits of pharmaceutical care, and this literature is expanding. Enhanced pharmacy services have led to improved detection, and substantial reductions in DRPs, as well as reduced health care use leading to substantial cost-savings. These benefits have been realized in diverse settings and patient populations. These reports, however, have been limited to retrospective reviews or controlled, prospective reviews of short duration and have centered on inpatient hospital care and services. Prospective, controlled trials of enhanced pharmacy services in an ambulatory setting are not yet available in the literature.

In a recent editorial, Dukes suggested that, to some extent, any monetary measures of adverse effects of drugs will be artificial and incomplete. We do not contend that this analysis conclusively determined the total cost of drug-related morbidity and mortality in the United States. Rather, we attempted to make estimates within a conceptual model that can be further developed and refined. The model should be tested in real-life settings, in specific populations, in geographic regions, or in integrated health care settings, and it should be modified as necessary. The frequency of, and cost of drug-related morbidity and mortality in the ambulatory setting in the United States is considerable, and this cost should be considered in health policy decisions with regard to pharmaceutical benefits.

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PRACTITIONER UPDATE

Outcomes Research, Pharmacoeconomics and the Pharmaceutical Industry

Diana I. Brixner

OBJECTIVE:
To review the basic principles behind outcomes research and pharmacoeconomics within the pharmaceutical industry.

DATA SOURCES:
Author's knowledge and recent pharmacy literature.

STUDY SELECTION:
Not applicable.

DATA EXTRACTION:
Not applicable.

DATA SYNTHESIS:
Various market forces have created the need for pharmacoeconomics research. The pharmaceutical industry has responded with the development of entire departments, interdisciplinary teams, or at least, functional responsibility within a specific position to meet this need. As is critical to any new business, the customers of this information must be defined. With this knowledge in hand, pharmacists can design and implement outcomes research and pharmacoeconomic studies to meet the specific needs of a targeted health system. The interdisciplinary nature of this field requires an organization structured to meet the diverse methodologic approaches used in these studies.

Various market influences are driving the emphasis on costs and quality of health care delivery in the U.S. The health care budget has received substantial attention over the last several years, and the increased rate of health care spending must be brought under control.

In this article, I review basic concepts of pharmacoeconomics and its relation to outcomes research. The responses of the pharmaceutical industry to the need for such information is also explored.

WHY DO PHARMACOECONOMICS?

Employers have recognized that the cost of health care benefits can have a dramatic impact on their bottom line.

These powerful forces have driven managed care plans to provide the employer with new options for health care at equal, if not better, quality at a lower cost. The initial reaction to this pressure was to negotiate discounts from hospital contractors, laboratory suppliers, and the pharmaceutical industry.

This scenario spawned the pharmacy benefit management company (PBM), which has been able to provide both managed care plans and employers with pharmaceutical products and services at guaranteed lower costs. The success of this short-term approach is evidenced by the significant drop in pressure felt by employee health care benefit managers over the last two years to reduce costs. However, once the ability to negotiate and provide lower costs has hit the minimum possible cost, the managed care and pharmaceutical industries must find new avenues to provide quality health care at lower costs.

Simultaneously, the consumers of health care are becoming more educated. Patients, employers, and payers want to know what they are getting for their health care dollar. If the value of pharmaceuticals is not demonstrated within this environment, then medications will be de-emphasized in health care budgets.

The practice of pharmacoeconomics and outcomes re-

CONCLUSION:
Armed with outcomes and pharmacoeconomic information, the pharmaceutical industry is far better situated to meet the challenge of integrating the use of pharmaceuticals into current practice.

KEY WORDS:
Pharmacy benefit management, Pharmacoeconomics, Industry, Managed care organizations, FDA, Outcomes research, Cost of care.

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search has emerged to define this value and demonstrate what the health care dollar is buying. This goes beyond the traditional proof of safety and efficacy of the product by including the description of the product's potential economic impact on a health care system. In the 1995 Zitter report on Pharmaceutical Outcomes Activities in the pharmaceutical industry, the number of outcomes activities decreased slightly despite a doubling of staff dedicated to outcomes activities. This trend seems to indicate an increased focus on outcomes research and pharmacoeconomic activities in the industry. Another trend of interest is the substantial increase in partnerships between the pharmaceutical industry and provider organizations in conducting outcomes research. Pharmacoeconomics can often be of great interest to the pharmaceutical industry because it provides valuable information on which products to develop.

**TERMINOLOGY**

The terms *outcomes research* and *pharmacoeconomics* must be distinguished from each other and various related words. The assessment of outcomes has been labeled out-comes research and is essentially the *total quality management* of health care.

Two key components of outcomes research include *outcomes management* and *outcomes measurement*. Outcomes management addresses the technology of measuring patient experience, while outcomes measurement defines the units for quantifying these outcomes. The process of health care delivery is tracked over time and the impact of particular health care choices on the patient's life is measured. Primary outcomes include medical resources used, cost of these resources, and quality of life.

A principal driver of outcomes research is the wide variation in practice patterns across the United States. Acute myocardial infarction may be treated differently at two different clinics within a managed care plan. The challenge of outcomes research is to determine which approach is most cost-effective, provides the best patient outcome, and find ways to have the same approach used in both areas.

Pharmacoeconomics is the most specific term in this arena. Pharmacoeconomics identifies, measures, and compares the costs and outcomes of using pharmaceutical products as a treatment alternative. The most important objective of pharmacoeconomics is to demonstrate the value of using a pharmaceutical product in treating a specific disease. That value is often much greater than the price of a drug may indicate. For example, if taking a pharmaceutical appropriately for one year prevents a hospitalization, the overall cost for treating a patient is decreased because the cost of the hospitalization would far outweigh the annual cost of drug therapy. An additional example would include drugs dosed multiple times per day versus once a day, in which additional pharmacy preparation and nursing administration time and decreased compliance would involve additional costs. The side effect profile of different therapies can also have an impact on overall costs. Some side effects may be easily managed with inexpensive medication, while other side effects may require expensive concomitant medication, complicate co-morbid conditions, or require additional treatment. Drug formulation may be an issue if a patient needs to extend a hospital stay because the drug is only available intravenously.

When a therapy is over-used in populations where a small group of patients will benefit, the average care cost per patient increases. On the other hand, if the population of patients can be identified where drug therapy will provide optimum outcomes, the cost per successful treatment can be substantially decreased.

*Pharmacoeconomics is the science of establishing this value for pharmaceutical products.*

**SOURCES AND USERS OF PHARMACOECONOMIC DATA**

Various health care systems are settings in which to conduct pharmacoeconomic research as well as users of pharmacoeconomic information.

**Hospitals** The hospital setting can provide excellent information on the care and cost of inpatient treatment. Hospitals also use pharmacoeconomic information to determine the impact of drug therapy on the length of stay for patients, as well as additional procedures that may be eliminated because of a particular drug therapy. In an institutional setting a pharmacist in charge of a drug budget may be reluctant to accept an expensive pharmaceutical product on the formulary. However, if pharmacoeconomic data can be presented to the pharmacist and/or the hospital administrator within the context of the overall cost perspective for the institution, the dimensions of decision making can be broadened. When used appropriately, pharmaceuticals can provide improved outcomes at equal or lower overall costs to the institution than current alternative therapy. As a hospital becomes part of an integrated health care delivery system, the pharmacoeconomic perspectives with which its personnel look at costs changes.

**Managed care organizations** Managed care systems can use pharmacoeconomic information since they are responsible for all aspects of care. They can also be a resource for pharmacoeconomic research through access to patient databases from either encounter data (staff or group model) or claims data (independent provider associations, preferred provider organizations, network models). When managed care contracts out to individual providers of care (i.e., physician groups, independent physician associations, hospitals, pharmacies, and long-term care facilities), attempts at conservation of costs are less coordinated among these individual groups. The managed care company reimburses each provider individually. However, in a staff or group model all providers of care take a personal and financial interest in keeping down the overall costs of health care delivery within their system. Therefore, the impact of pharmacoeconomic therapy on the various stages of an in-
Table 1. Definitions of the Four Classic Pharmacoeconomic Models.

Cost-effectiveness. An analysis that compares two or more interventions in terms of both total resources used and health outcomes achieved. Outcomes may be described as costs, charges, years of life saved, or days of hospitalization prevented.

Cost-utility. A type of cost-effectiveness analysis that evaluates costs and consequences of an intervention in terms of the patient’s quality of life, ability to absorb cost, or preference for one treatment over another. Expressed as cost per quality-adjusted life-year (QALY).

Cost-minimization. An analysis of two or more treatments deemed to be comparable effective so that cost is the only differentiating factor. Also known as cost-identification analysis, cost-minimization compares direct medical costs.

Cost-benefit. In cost-benefit analysis, all costs (inputs) and benefits (consequences) of alternatives are measured in monetary terms. The outcome may be expressed as a ratio (benefit to cost) or in terms of net cost or benefit (benefit minus cost).

individual's overall care are more relevant.

Pharmacy benefit management companies PBMs have traditionally focused on managing pharmaceutical costs for their managed care or employer clients. However, they are rapidly moving towards using pharmacoeconomic data in making formulary decisions that will produce the best overall economic outcome for their clients. This phenomenon has been recently described by Blissenbach as a move from determining total drug costs to calculating total medical costs. These two concepts are then combined to arrive at the “value equation” where value equals outcomes over costs.

As this trend emerges, PBMs will be able to use pharmacoeconomic data to justify an increase in per-member, per-month fees for the drug capitation that will result in further decreased medical costs. In the absence of these types of analyses, the PBM will no longer be able to remain competitive as a carved-out benefit.

PBMs can also provide pharmaceutical claims information for the conduct of outcomes and pharmacoeconomic studies. As these organizations begin to work more closely with their managed care clients, they will also be in a position to offer integrated databases that incorporate the medical claims of their clients.

Integrated health care delivery systems As different providers join together to offer a continuum of care for patients, pharmacoeconomic information becomes of greater value. These systems are also in the process of creating information networks that incorporate data from each of the different provider areas. These data networks will be useful for conducting outcomes research projects. As these systems become more integrated, the emphasis on demonstrating the value of pharmaceutical therapy will be redirected toward the impact on overall health care costs.

Government Medicare and Medicaid programs are exploring various options for providing managed care and are becoming interested in data on the outcomes and usage of drug therapy. Pharmaceuticals are currently not covered for the elderly under Medicare. However, if patients are moved into a managed care program, a key inducement will be prescription drug coverage. These dynamics should provide valid data on the impact of prescription coverage on overall treatment costs for the elderly.

Medicaid programs can provide access to claims data for both medical and pharmacy services. These databases are an excellent resource for conducting retrospective analyses. However, the impact of pharmacoeconomic information is less pronounced in government-based care. Despite the agreement in principle of managing overall health care costs, most governments operate on an annual budget that promotes a more short-term outlook on costs, leading to the compartmentalization of budgets.

Food and Drug Administration The FDA focuses primarily on the aspect of promotion of pharmacoeconomic information. Currently, the FDA has no regulations for the design of pharmacoeconomic studies for promotion; however, the agency recommends that such evaluations be based on two randomized, well-controlled clinical trials. These recommendations differ significantly from the pharmacoeconomic needs of managed care customers and make FDA a unique customer for pharmacoeconomic information intended for promotional use.

In general, the design of a pharmacoeconomic study depends on the desired perspective customer group. A recent article by Draugalis and Coons provided a report of a conference that explored the facilitation of pharmacoeconomic research between academia, managed care organizations (MCOs), and the pharmaceutical industry. One of the key learnings from this conference was that the challenge to the pharmaceutical industry is to design studies sensitive to how the results will be accepted and used by the MCO. An even greater challenge will be to anticipate the needs of emerging customers such as employers and business coalitions, either directly or through the MCO.

CUSTOMIZED PHARMACOECONOMIC MODELS

The classic terminology used in describing pharmacoeconomics includes the four models described in Table 1. Although these models provide the foundation of pharmacoeconomics, any one individual model often does not
Table 2. Primary Objectives of U.S. Pharmaceutical Outcomes Research Group

- Assist in the design of worldwide pharmacoeconomic studies.
- Design pharmacoeconomic and outcomes research studies to support the U.S. market.
- Establish collaborative relationships with academia and the managed care industry in the area of outcomes research.

meet the specific needs of the customers of pharmacoeconomic data. Although the traditional models are critical in the design of pharmacoeconomic projects, the following definitions are a more practical description of the types of research projects often undertaken.

Cost of care evaluations provide models for the current cost of providing care for a particular disease state. They examine the natural history of disease and the medical resources and costs associated with treating that disease in a specific practice setting. An important distinction between a cost of care versus a cost of illness (COI) evaluation is the fact that a COI study will often be conducted from a societal perspective and include associated indirect costs secondary to the disease. In a cost of care model, the perspective is more often that of the payer and, therefore, indirect costs are of less interest. These types of projects provide information of benefit to both the MCO and the pharmaceutical industry. The MCO gains a detailed perspective on how a certain disease is managed within the plan, and the pharmaceutical industry obtains information on the potential economic impact of its product.

Phase III economic trials are those that collect data on economic parameters of drug therapy from the patients participating in Phase III clinical trials. This provides valuable economic information about the drug at the time of launch. A disadvantage of this approach is that the economic parameters may be driven by the clinical trial protocol and therefore may not reflect “real world” use of the drug. Drummond6 summarizes the specific methodologic issues that arise when integrating economic and clinical research such as design, collection of resources-use data, collection of outcomes data, and the interpretation and extrapolation of results.

Naturalistic prospective evaluations are designed to address the limitation of Phase III economic trials by prospectively collecting the economic parameters of a drug and its most relevant therapeutic alternative within a specific practice setting with minimal intervention. Although these studies can often provide valuable information towards therapeutic decisions, a disadvantage is that they can be time consuming and expensive.

Retrospective database analysis of prescription and medical claims within a specific practice setting can provide useful information in a short period of time at little expense. Information on the trends of prescribing patterns can be particularly helpful. A disadvantage is that claims may not be an accurate reflection of actual care received if claims are submitted to maximize reimbursement.

Decision analysis modeling is an approach that uses information from epidemiologic studies, clinical trials, administrative claims and cost databases, and expert opinion to model current care and the impact of a specific new therapy. These models can be very useful in designing prospective economic trials as well as offering predictions on the impact of a pharmacoeconomic agent in the treatment of disease. Because it is not always possible to study all the effects of treatment with clinical trials, modeling techniques can be very useful in making therapeutic decisions. These principles were recently reviewed by Stergachis.6

HOW IS PHARMACOECONOMIC INFORMATION USED?

Once this information has been gathered, the challenge is how to use the information. Several areas of clinical practice have incorporated pharmacoeconomic data in relative decision analyses.

Pharmacoeconomics clearly defines the overall economic impact of drug therapy within all medical areas and presents the overall financial impact on a health care system.

An economic analysis of a particular drug can be especially useful in formulary decision making. A more expensive drug may decrease costs in other medical areas and could, therefore, be considered for the formulary. Often a drug will be cost-effective within a specific patient population. This information can be incorporated into clinical practice policies or guidelines that describe how the drug can be used most efficiently to treat a specific disease or symptoms.

With pharmacoeconomic information in hand, caregivers can identify the true value of a drug to a health care system. This information can be used in price negotiations to support a pharmaceutical price premium or discount within a specific plan.

OPERATIONAL PHARMACOECONOMICS WITHIN THE PHARMACEUTICAL INDUSTRY

How all this information is integrated into a pharmacoeconomic department within the pharmaceutical industry varies as much as the different approaches to conducting these studies. Pharmacoeconomic or outcomes research departments can be under the wing of marketing, clinical development, a product strategy group, or various other locations. At Ciba Pharmaceuticals, the Department of Pharmaceutical Outcomes Research is based in the Policy and Business Development function. This geography allows for interactions with various departments, such as clinical development and marketing, while maintaining a specific identity for the pharmacoeconomic function.

The three principal functions of the U.S. Pharmaceutical Outcomes Research group at Ciba are described in Table 2. A secondary issue is whether a pharmacoeconomic or outcomes research function is part of a global initiative or a country specific-function. Since so many pharmaceutical companies are
moving toward global research and development initiatives, the incorporation of pharmacoeconomic parameters into clinical trial design must also be globalized. However, in the area of pharmacoeconomics, this can pose several serious challenges. As countries make reimbursement decisions they are also developing country-specific guidelines for the conduct of pharmacoeconomic research in support of their decisions. Not surprisingly, the guidelines differ between countries. Another difference involves the practice patterns of care and the currency in which reimbursement takes place.

Because of all these market variances, the pharmaceutical industry should be represented by a global pharmacoeconomic strategy in conjunction with a global clinical research plan. The customer markets of the United States, principally managed care organizations, play a major role in the design of global pharmacoeconomic studies before launch. Therefore, a principal responsibility of a U.S.-based outcomes and pharmacoeconomics group should be to serve as a liaison between the country market and the global pharmacoeconomic function.

To serve this function as a liaison, two important strategies have emerged. First, the incorporation of managed care sites into global clinical and pharmacoeconomic trials will provide managed care with a comprehensive understanding of the safety and efficacy of a product, within the health plan environment. This will allow informed decisions to be made at the time the product becomes available based on the performance of the drug in a managed care population. From the patients' perspective, they will have access to appropriate new therapies more quickly. Second, managed care should become more involved in designing market-specific models to augment the results available from global pharmacoeconomic studies. This would include both development of "cost of care" models for specific disease states and models to evaluate where the drug will be best positioned for maximum cost-efficiency once available.

CONCLUSION

In the current health care environment, all pharmaceutical products must provide the most beneficial outcomes at the lowest cost to patients, health care systems, and society at large. As an aid in managing this responsibility, the practice of outcomes research and pharmacoeconomics has emerged. Studies are being designed to meet the specific needs of the various providers of health care when making therapeutic decisions that include drug therapy. Pharmacoeconomic departments within the industry need to be structured to maximize the opportunity of incorporating economic parameters into ongoing clinical trials while at the same time providing data of practical use to the customers. Armed with outcomes and pharmacoeconomic information, the pharmaceutical industry is far better situated to meet the challenge of integrating into current practice.

References

MANAGED CARE PHARMACY EDUCATION AT MCP

Managed care is a concept here to stay, and it will control an ever-increasing segment of our health care delivery system. As a result, health professional schools, including pharmacy, have a responsibility to ensure that graduates of their programs have at least a basic understanding of managed care principles.

In Boston, we often say that changes in pharmacy in the United States move from west to east. With respect to managed care pharmacy, we have tried to alter this precept. At the Massachusetts College of Pharmacy and Allied Health Sciences, we have made a commitment to provide leadership in managed care pharmacy education. To that end, we have developed required and elective didactic courses, experiential rotations, postgraduate residencies, and fellowships to ensure that our graduates are prepared to practice in a health care environment in which managed care plays a prominent role.

Students in both our baccalaureate and track-in Pharm.D. programs are first exposed to managed care in a health care systems course required of second year students (second preprofessional year in our 0-5 and 0-6 programs). The managed care module in this course includes a basic discussion of managed care principles, terminology (e.g., prospective reimbursement, capitation), and models (e.g., HMO, PPO, IPA).

Students are required that same year to take a course in pharmacy management in which managed care is explored from the business perspective.

Fourth-year students (second professional year) take a course in pharmacy ethics that addresses specific issues in managed care such as “freedom of choice.” For those students with a greater interest in managed care, an elective, computer-assisted, managed care course, developed by a MCP/AHS faculty member, provides a more in-depth discussion of managed care concepts and systems.

The experiential educational component of our curriculum includes both ambulatory externships and clinical clerkships at managed care sites. Currently, MCP/AHS students are required to complete a five-week hospital externship, a five-week ambulatory externship, and an eight-week clinical clerkship.

Because of the absence of hospitals managed or owned by managed care organizations in the greater Boston area, we have been unable to establish externship rotations in acute managed care. However, our ambulatory externship program has several well-established rotations at managed care sites, including Harvard Pilgrim Health Care and HMO Blue/Medical West. The externship rotations at these sites allow the students to see practical applications of managed care principles as they relate to drug distribution, formulary management, and patient care.

Clinical clerkship rotations at managed care sites are also available to MCP/AHS students. At these sites, students are exposed to the diagnosis and treatment of disease from a managed care perspective.

During the next academic year, the college will switch from a quarter to a semester system. The externship and clerkship programs will be merged into a single 16-week experiential rotation. With this change, the use of managed care sites for experiential instruction, which can provide students with both distributive and clinical experiences, will become even more commonplace.

MCP/AHS offers one of the few postgraduate managed care pharmacy residencies in the United States. The residency is a partnership between the College and Harvard Pilgrim Health Care and is currently in its fourth year. The goal of the one-year program is to prepare individuals who will assume important roles in managed care pharmacy practice. Residents complete both administrative and clinical rotations, take several postgraduate courses, teach in an undergraduate laboratory, and complete one or more projects, both research-based and nonresearch-based.

More recently, the College has begun a postgradu-
MANAGED CARE AND PHARMACY: COMPARING THE UNITED STATES AND GERMANY

Editor's note: With this issue, JMCP inaugurates a periodic sharing of international comparisons of interest to AMCP members and JMCP readers. Health care system developments in other nations often illuminate our own perceptions of U.S. health care, as well as help us reconsider health policies in the U.S. Forthcoming articles will seek to report experiences elsewhere with parallels to the U.S. Submissions should be addressed to J. Warren Salmon at the address listed below.

This first rendition summarizes a conference held in Magdeburg in the former East Germany, which is undergoing great change since the country's unification in 1989.

HEALTH POLITICS: MANAGEMENT AND CONTROL OF DRUG INFORMATION

In the Federal Republic of Germany (the union of the former East German and West German republics), traditions, laws, and regulations provide a health care framework different from that in the U.S. in several crucial respects. First and foremost is universal health insurance coverage for all German citizens, provided mostly by so-called "sickness funds," not-for-profit insurance entities tightly scrutinized by the federal government that offer almost indistinguishable health benefits packages for comparable contribution rates for workers and employers. Second, all essential drugs are covered by these various sickness funds, including those for the nonemployed public beneficiaries. Third, drugs can only be obtained in licensed pharmacies, where prices are the same all over Germany. Lastly, no chain pharmacies exist because a pharmacy owner (who has to hold a pharmacy degree) is by law not allowed to own more than one pharmacy.

Despite such differences (of which only a few pertinent ones are mentioned here), Germany, like most countries, faces ever-rising health care costs (currently at 9% of the German gross national product, versus 14.2% in the U.S.). In the past, Germany has been much more successful in containing the rate of growth in health care costs. The annual cost per capita was $1,659 in the FRG versus $2,867 in the U.S. in 1991. Legal reforms have contained expenditures by changing pharmaceutical prescribing patterns to decrease the use of "therapeutische umstrittene Arzneimittel" (therapeutically questionable drugs). The German federal government recently resisted implementing a national formulary, even though it would have lowered prescription drug costs. Calls for outcomes research, quality assurance, and cost-benefit analyses have therefore begun to be mentioned in the political debates.

Embedded in the quest for greater provider accountability and patient empowerment, the topic of drug information—how it should be performed, and by whom—was the center of a day-long discussion of the Program in Health Promotion at the Fachhochschule Magdeburg, Germany, on July 5, 1995. Initiated and moderated by Professor Eberhard Goepel, M.D., this workshop was organized in cooperation with the State Association for Health Promotion and the Association of Sickness Fund Physicians in the state of Sachsen-Anhalt, situated south of Berlin. Support came from the Ministry for Work and Social Issues in Sachsen-Anhalt (in the former East Germany). Of special interest to the German participants (the majority were pharmacists from different job responsibilities) were the contributions from American colleagues, who shared their insights and experiences with managed care and pharmacy benefits management organizations (PBM)—models of health care provision which are new to the German market, but are receiving increased consideration in the ongoing health care reform debates.

Professor Dr. Andreas Geiger, Dean of the Fachhochschule Magdeburg and President of the State Association for Health Promotion, emphasized the important role of drugs in health care. In his opening address, he stated that inappropriate drug use all too often leads to undesirable consequences, such as drug dependency, allergic reactions, and drug interactions—negative outcomes that point to the necessity of educating patients to become informed and responsible participants in their own therapeutic processes. Questions such as how this task can be performed (by whom; which professional groups, institutions, and organizations should take part, and whether they might cooperate or counteract each other) were introduced by Prof. Goepel as leading themes discussed at this workshop.
DRUG-USE INFORMATION AS A PRECONDITION FOR CONTROL MEASURES —

Having at one's disposal information regarding drugs, drug markets, and drug consumption are not only preconditions but also necessary instruments for the implementation of control measures in health care politics. In her overview, Dr. Ingrid Schubert (Medical Institutions, University of Cologne) demonstrated how in Germany, such types of information have so far been used in the pursuit of achieving health care political goals, such as organizing drug safety, stabilizing costs, and assuring quality of drug prescriptions.

Regulations governing these areas in the U.S. are less restrictive, thus allowing for a broad diversity of business arrangements in terms of pharmacy ownership and methods of drug distribution. Professor J. Warren Salmon, Ph.D. (Social and Administrative Pharmacy and Public Health, University of Illinois at Chicago), described the growing corporatization in the American health care system, especially the resulting impact on the role of pharmacists in the delivery of health services. The number of independent community pharmacies has been decreasing steadily in favor of huge chain pharmacy conglomerates, in which drug dispensing plays only a subordinate role among many other consumer goods being sold in such enterprises.

According to Dr. Salmon, market developments deserving particular concern are the recent take-overs of mail service and pharmacy benefits management firms by some pharmaceutical manufacturers. This type of vertical integration into drug distribution makes it possible for pharmaceutical companies to exert stronger influences over physicians' and pharmacists' therapeutic and counseling and decision-making processes. Salmon warned the German participants that concepts and models of health care re-organization, which have not yet been fully evaluated in the U.S. context, should not be thought of as easily transferable to other countries' systems. European policymakers seem enamored by the marketplace rhetoric from the U.S., but caution should be taken until more solid experience and evidence are available showing consumers benefits in terms of general health improvements.

New organizational structures in health care can also allow for new forms of access to information about physicians' prescribing behaviors, as well as patients' drug-use patterns, through the implementation of new information technologies. Ulrike Wigger, M.S. (Social and Administrative Pharmacy and Health Information Management, University of Illinois at Chicago), described the current use and expansion of such technologies in the U.S., while also pointing to questions that arise from the accompanying standardization of many health care services. Of particular concern to her were tendencies for automatically equating the potential for standardization, measurement, and statistical accuracy with increasing efficiency and improving clinical outcomes. When assessing physicians' performance, too much emphasis on productivity is dangerous since some dimensions of health care are not easily amenable to measurement (such as long-term care for the chronically ill and allowing for often therapeutically necessary idiosyncrasies of physician-patient relationships).

ASSURING SAFETY IN DRUG USE —

Professor Dr. Marion Schaefer (Social Pharmacy, Humboldt University, Berlin) started her presentation with the assumption that important steps toward assuring drug-use safety and therapeutic efficiency could be made, if information and communication gaps among health professionals and their patients could be removed. Dr. Schaefer argued that community pharmacies should be seen as a location in which huge contributions toward assuring drug safety could be achieved. The process of providing drug information requires knowledge about a patient's attitude toward drug therapies and answers to how patients handle such types of information; both are not well researched. A goal of the concept of pharmaceutical care (borrowed from U.S. pharmacy) is to avoid drug-related problems in patients via methods of prevention and early recognition. According to Dr. Schaefer, an important tool to facilitate the performance of such tasks is the so-called "chip card"—a magnetic card designed to keep track of all the drugs dispensed to a patient and other health-related information.

Documenting and monitoring physicians' prescribing behaviors was described by Dr. Ulrike Faber (AOK Berlin, a public sickness fund) as the basis from which sickness funds engage in pharmacologic and pharmacoeconomic counseling of physicians—in itself an indispensable contribution to quality assurance in prescribing behaviors. The sickness funds (which in effect finance almost all therapies, including drugs) are interested in achieving higher quality health services. Counseling, especially where physicians are concerned, is seen as a crucial task.

To date, the German sickness funds can analyze a physician's practice patterns in terms of economic and therapeutic criteria, based on data that include patient demographics, prescription costs, and types and brands of drugs prescribed on both office-wide and per-patient bases. Without the feedback of hard data, German physicians often have difficulties estimating their own prescribing behaviors, especially when it comes to the use of tranquilizers and multiple medications for the same indications. With several examples of inappropriate prescriptions, Dr. Faber demonstrated that even though an overabundance of drug information is theoretically available, information gaps and/or difficulties in the practical application of drug information do exist, and these pose continued real public health problems.

In contrast, the medical profession—represented by
E. Penndorf, M.D. (Association of Sickness Fund Physicians, Sachsen-Anhalt), sees neither patient nor physician counseling as a task that should be defined by the sickness funds. Dr. Penndorf urged the sickness funds to provide medical associations with the information regarding physician and patient profiles, so that physicians themselves could alter their own prescribing behaviors and manage their drug budgets. To foster information exchange and communication among health professionals, Dr. Penndorf suggested improvements in the content of referral forms and ease of collegial networks, especially when it comes to linking the ambulatory and hospital sectors, which in Germany remain under separate medical control.

**DRUG INFORMATION VIA THE TELEPHONE**

Performing patient counseling via the telephone is possible for physicians, pharmacists, sickness funds, self-help and consumer organizations (after the patient has read about his or her medication at home), and the pharmaceutical industry. The Bundesverband der Pharmazeutischen Industrie (BPI), the trade association of the pharmaceutical industry in Germany, has started a telephone service for patients. As reported by Dr. Dagmar Walulf-Blume (BPI), this organization was surprised at the high volume of patient calls. A primary goal of BPI is to contribute to the safe use of drug products, especially in self-medication (comparable with that pursued with the provision of patient information leaflets and package inserts). For questions that cannot be dealt with over the telephone, or in cases of uncertainty, patients are encouraged to talk to a physician and/or pharmacist.

In case of drug-related questions, people in Germany also can contact the Bundesinstitut fuer Arzneimittel und Medizinprodukte (comparable in its tasks to the U.S. Food and Drug Administration). Dr. Ulrich Hagemann (Bundesinstitut fuer Arzneimittel und Medizinprodukte, Berlin) discussed the institute's informational tasks, legislative aspects of patient package inserts and drug advertisements, and factors that influence how much (or how little) actual drug information is presented to the regulatory agencies for transmission to the public. Dr. Hagemann stated that whatever information reaches the agency forms only the "tip of an iceberg" of all information available at the producing company.

The lively discussion among the workshop's participants showed differences in opinions, especially when it came to task assignment and take-over of responsibility for the provision of drug information. However, goals such as increasing accountability and safety in reaching optimal therapeutic outcomes were common to all participants.

From the American perspective, many topics on the U.S. agenda are being currently discussed in Germany (i.e., improving communications and integrating the ambulatory and hospital sectors to reduce unnecessary referrals and duplications of diagnostic tests). Discussions at the workshop centered around who (at the exclusion of others) should be responsible for providing drug information to the patient, and whether patients are "mature" (muendig) enough to either take part in or to make their own decisions about their care. Too much information, as well as too many sources of information, was seen as potentially confusing to patients. In contrast, Americans embrace patient empowerment using multiple information sources (e.g., schools, media, voluntary health agencies, government, provider agencies, physicians and pharmacists, consumer books, and now the Internet).

This particular German discussion focused mainly on who should provide drug information to patients, whereas the American participants were more concerned about the implications of who controls and channels drug information to both the providers and patients. In the U.S., commercial profit motives in a relatively deregulated health care market place are increasingly impinging upon physicians' clinical autonomy and therapeutic decision-making processes. In fact, physicians find themselves often in the dilemma of dual, but contradictory, allegiances to their patients, for whom they want to provide the best care possible, and insurance companies or physicians' employers (managed care organizations), on whom they depend for their own economic livelihood but who might not pay for what physicians deem therapeutically appropriate.

Commercial interests increasingly dictate the numbers of patients a physician sees in an hour and also the number of prescriptions a pharmacist is expected to fill everyday. In other words, business interests are often setting the practice conditions for clinical work.

Proposed changes for the German health care system seem to focus on increasing the competition among providers and introducing further market-driven incentives, all of which will affect the channels of drug information and distribution. Therefore, U.S. experiences should be taken into account, with reflection on the following questions about the German context:

1. Given a relatively deregulated marketplace, how and by whom will patient and provider data and other sensitive information be collected, analyzed, and evaluated? Who will have purview over such information? And for what purposes will it be used (cost reductions, increasing quality, profit enhancements, public health improvements)?
2. To what extent is it possible to introduce market-driven incentives without endangering the principles of solidarity and equal access embodied in universal health care coverage to health care?
ASTHMA DISEASE MANAGEMENT: INTEGRATION OF DUR, CASE MANAGEMENT, AND PERFORMANCE INDICATORS

Using an asthma disease management program as an example, methods are described in this Profiles article that assist in the integration of drug-use review, case management, and performance indicator data in a disease management program. The use of inferred diagnosis, diagnostic procedure, and medical encounter data, as well as performance assessment tools, are discussed.

Trigon Blue Cross Blue Shield (Trigon) decided to pilot a disease management initiative by using patients and physicians already enrolled in an asthma outcomes study. Trigon is participating in the nationwide Outcomes Management System Project sponsored by the Managed Health Care Association. Heritage Information Systems (HIS) provides Trigon with DUR, auditing, and pharmacotherapeutic consulting services. HIS-integrated pharmacy claims data from the claims processor, and diagnostic/encounter data from the insurer are entered into a complete patient profile. The goals of this effort were to: (1) show individual prescribers their medical results and give them some tools for improving outcomes; and (2) use the existing Comprehensive Case Management (CCM) program to further the aims of the project.

Since Trigon had already developed and approved clinical practice guidelines for the treatment of asthma, the next step was to determine the best opportunities for the greatest improvement in asthma treatment. A total of 309 physicians were enrolled in the study. Complete claims, diagnostic, and encounter data were available for 594 patients. The number of patients per physician ranged from 1 to 12, with a mean of 1.9.

Outcome, process, and use indicators were developed, tested, and used to assess performance and adherence to the practice guidelines. A total of 23 indicators were developed and tested. Results of preliminary indicators showed that: (1) 40% of the study patients receiving salmeterol did not have a documented claim for a short-acting β2-agonist inhaler; (2) the number of asthma patients with an emergency room (ER) visit who did not have a steroid inhaler ranged from 50% to 88%; and (3) about 60% of patients receiving a chronic oral asthma medication or ipratropium were not using a steroid inhaler.

Based on the results obtained from the 23 preliminary indicators, the following 10 indicators were chosen to be included in a disease management profile:
1. Admissions/year/patient
2. Number of ER visits/year/patient
3. Number of office visits/year/patient
4. Percentage of patients with asthma medications without a prescribed steroid inhaler
5. Percentage of patients with ER visits without a prescribed steroid inhaler
6. Percentage of patients receiving salmeterol without a prescribed short-acting β2 agonist
7. Significant drug–drug interactions/1,000 patients
8. Number of specialty visits/patient/year
9. Medical costs/patient/year (excluding drugs)
10. Costs of drugs/patient/year

This disease management profile summarized the results of 10 performance indicators for the study patients for whom complete data were available. Since eligibility data linking the primary care physician and patient were not available at the time of this project, the profile provided information about patients enrolled in the asthma study who were prescribed an asthma-related drug by a physician. Summary information was available about all study participants. Physicians were informed that the profile was for their information only, and that Trigon realized: (1) they may not have a primary responsibility for management of the patient's asthma; and (2) inferences about their management of asthma could not be made because of the small sample size and other statistical considerations.

The claims and diagnostic data for patients enrolled in the asthma study were reviewed for both potential asthma-related and other drug-related problems. If problems were detected, DUR profile review letters were included in this package. A "no problems detected" letter was included if there were no drug-related problems found in the profile review.

To increase the patient's involvement in the continuous monitoring of their own health status, the CCM program offered free peak flow meters to all patients participating in the study. Since asthma is a disease that may not be documented in all cases, Heritage assisted the CCM unit in the identification of potential participants in the CCM program. Using claims data alone, an "inferred" diagnosis was made based on the use of chronic asthma medication.

This project had several limitations. As mentioned previously, PCP data were not available at the time of this study, so the prescriber of asthma medication may not have had primary responsibility for management of the patient's asthma. Case severity or specialty were not considered for this project. Despite these limitations, the disease management profile was well received by the physicians participating in the asthma study. This will be used as a model for other disease management efforts.

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PHASE I/II

▲ More positive docetaxel (Taxotere, RPR) news emerged in Paris at the eighth annual European Cancer Conference. Results of a Phase I study indicated that a combination therapy with doxorubicin (Adriamycin) appeared effective in 12 of 14 patients with metastatic breast cancer.
▲ Biogen has begun Phase I trials of LFA3TIP, an anti-inflammatory compound, for treatment of psoriasis at London’s Guy’s Hospital.

PHASE III

▲ Based on the opinion that more data are needed, an FDA advisory panel recommended against approving INFORM HER2/neu—an Oncor gene-based breast cancer test designed to help patients identify recurrence of breast cancer. The HER test can also identify which small tumors are likely to recur.
▲ An FDA advisory panel has recommended approval of Verulima (NeoRx Corp.), a diagnostic imaging agent composed of a monoclonal antibody fragment linked to technetium 99m and used in staging small-cell lung cancer.

POSTMARKETING

▲ The National Cancer Institute is sending advisories to cancer specialists saying that tamoxifen should be used for a maximum of five years in breast cancer. Large clinical trials showed no benefits—and possibly some problems—from use after five years.
▲ An FDA advisory panel recommended approval of 3-TC (lamivudine) for treatment of HIV and hepatitis B. First of a new class of antiviral compounds, lamivudine inhibits the enzyme protease which is necessary for viral replication. Glaxo Wellcome will sell lamivudine in the U.S. under the tradename Epivir, while the originator company BioChem Pharma will market the drug in Canada. Additionally, OncorRx of New Haven, Conn., holds marketing rights for 3-TC for use in treatment of hepatitis B virus.

Against HIV, lamivudine will be used in combination with zidovudine (Retrovir). The four clinical studies that form the basis of the new drug application indicate that the drug combination significantly increased the number of the body’s CD4 cells, while reducing the number of HIV cells in patients’ blood. The most common adverse effects were headache, nausea, malaise/fatigue, and nasal symptoms.
▲ Pharmacia launched dalteparin sodium (Fragmin), the first once-daily low molecular weight heparin, at the American College of Surgeons meeting in the last week of Oct. The product is for prophylaxis against deep-vein thrombosis in abdominal surgery patients at risk for thromboembolic complica-

ions.
▲ FDA approved saragrostim (Leukine, Immunex) for use following allogenic bone marrow transplantation from HLA-matched donors.

▲ Docetaxol (Taxotere, Rhone-Poulenc Rorer) was approved by the European Commission for use in breast cancer patients.
▲ The first retinoid or vitamin A derivative for oncologic disorders was approved by FDA. Tretinoin (Vesanoid, altretrex retinoic acid, Roche) is indicated for treatment of acute promyelocytic leukemia in the 50% of APL patients who are refractory to, have relapsed after, or have contraindications for standard anthracycline chemotherapy.

Side effects include 25% of patients who experience retinoic acid—APL syndrome—fever, weight gain, and shortness of breath with or without an increase in WBCs. Progressive hypoxemia from the syndrome can cause death. Patients should be treated with high-dose steroids at first sign of the syndrome. The drug is highly teratogenic.

Vesanoid is available in 10-mg gelatin capsules, and the product is contraindicated in patients sensitive to retinoids or parabens.
▲ Liposome products containing amphoteratin B and doxorubicin were approved by FDA. Ambicet (Liposome Co.) will be used for treatment of aspergillosis in cancer and bone-marrow-transplant patients. Doxil (Sequus Pharmaceuticals) was OKed by the agency for treating Kaposi’s sarcoma in AIDS patients.

Liposomes are microscopic fat “bubbles” that carry the drug to its site of action with fewer systemic effects. For instance, the amphoteratin B product is able to deliver more anti-infective to the site of fungal infection without producing the renal toxicity common with that agent.
▲ A novel, insulin-sparing sulfonylurea, glimepiride (Amaryl, Hoechst Marion Roussel), has been marketed in the U.S. for treatment of type II diabetes mellitus. The agent, for the first-line therapy to control type II DM when not controlled by diet and exercise, is being launched in 1996.

Glucose control was achieved in clinical studies of glimepiride in a broad range of patients, including obese patients, those with hypertension, and traditional at-risk populations such as Hispanics and African-Americans. Because the agent spares insulin, the risk of hypoglycemia is markedly reduced.
▲ An FDA advisory committee has recommended easing constraints on the marketing of Fentanyl Oralet. Approved in 1993, the Anaest Corp. oral transmucosal product has been distributed by Abbott to a limited number of hospitals for use as an anesthetic premedication.
Express Scripts, Inc. goes interactive on the Internet’s World Wide Web. It is the first site in the industry to employ interactive forums for third-party administrators and managed care organizations; frequently updated company information; and links to dozens of health care-related Internet sites. Professionals from around the country can post messages about developments in their fields on electronic bulletin boards, as well as send electronic messages to each other and Express Scripts. The focus of the Internet site is the discussion forum section. http://www.expressscripts.com.

SMG Marketing Group, Inc. has released SMG VantagePoint, a Microsoft Windows-based software system that allows users to select search criteria for access to more than 30 SMG Health-care Market Data Network databases, and integrate requested data into a wide range of analytical reports; 708/540-0821.

The publishers of Physicians’ Desk Reference have released a new reference titled Physicians’ Desk Reference Generics. A comprehensive source of generic pharmaceuticals organized alphabetically. PDR Generics is available nationwide in bookstores for $69.95, 201/358-7500.

Therapeutic Drug Monitoring is a new textbook by Gerald E. Schumacher, Pharm. D., Ph.D., that covers in detail the drugs commonly monitored using serum drug concentrations as adjuncts to decision-making. It is also a reference that contains material not presently available in other textbooks on TDM, such as how drugs are monitored, the total testing process used by the clinical laboratory to process and interpret serum drug concentrations, test performance criteria describing the usefulness and limitations associated with using serum drug in decision analysis, and the template for characterizing outcomes of TDM from both system-related and patient-centered viewpoints. Each chapter begins with points “To Keep in Mind,” and concludes with a summary of essential concepts and the opportunity to test knowledge through questions and cases with answers; 203/838-4400.

Williams & Wilkins has released Steadman’s Medical Dictionary, 26th Edition containing over 800 full-color illustrations, photos, and tables, 12,000 new terms, and easy-to-find English translations of Latin anatomy terms. It is available in leather cover ($89.95), DOS/WIN, Macintosh, or CD-ROM ($129.00); 800/527-5597.

Children’s Medications: A Guide for Schools and Day Care Centers is now available to provide teachers, day care providers, and school nurses with comprehensive information on children’s medications. Published by Harvey Whitney Books Company, this reference outlines dosage, drug interactions, side effects, administration, storage, and special precautions for each drug. The only comprehensive resource available in the U.S. that focuses on medication use in children attending schools or day cares. ($29.95); 513/793-3555.

Also available from Harvey Whitney Books Company, Children’s Medications: A Parent’s Guide. This reference gives parents comprehensive, easy-to-understand information about their children’s medications, including both prescription and over-the-counter medications, and information for all age groups—from infants through adolescents ($19.95); 513/793-3555.

The 40th Anniversary Edition of American Drug Index is now available from Facts & Comparisons. It contains more than 20,000 entries listed alphabetically, including recently released drugs, orphan drugs, new dose-forms, and updated manufacturer listings ($49.50); 800/223-0054.

Listings and analyses of new books, periodicals, audiocassettes, videotapes, software, and other communication vehicles are provided in JMCP’s Media column. Announcement and review copies should be sent to the Editor at PO. Box 6565, Athens, GA 30604.

New Releases

Hospital Smarts is a new “handbook” by New York docs Theodore Nyberg and Kenneth Rothstein that exposes those little known facts about acute care for American consumers: why your hospital bill is $69,999, not $69,955; why you should not have elective surgery in July; who wears the longest white coat, and what the ER is really like. It is available in cloth or paper ($24.95); 212/486-4959.

The 1996 Behavioral Outcomes & Guidelines Sourcebook is a complete, unbiased compendium of outcome and guideline researchers. It is a 15-day task-free examination period and purchased for $269.95; 800/535-8403.

Patient Drug Facts is available in print and software versions in English ($75) or English-Spanish ($175). Each version includes quarterly updates for 12 months, and is available from Facts & Comparisons; 800/826-0555.
EVENTS

▲ 1996 Health and Disease Management Congress
February 25-27, 1996
Dallas, TX
Contact: The Zitter Group
90 New Montgomery, 8th Floor, San Francisco, CA 94105;
800/210-7158.

February 25-27, 1996
Washington, DC
▲ Understanding Managed Care: An Introductory Program for Managers New to Managed Care
April 18-21, 1996
Atlanta, GA
Contact: GHAA/AMCRA
Department Number 0612
Washington, DC 20036;
202/778-3269.

▲ Eighth Annual National Managed Health Care Congress
April 28-May 1, 1996
Washington, DC
Contact: NMHCC, 70 BLanchard Rd., Suite 4000,
Burlington, MA 01803;
617/270-6000.

▲ AMCPs Eighth Annual Meeting
May 9-12, 1996
San Francisco, CA
Contact: Academy of Managed Care Pharmacy,
1650 King St., Suite 402,
Alexandria, VA 22314;
800/TAP-AMCP.

▲ XI International Conference on AIDS
July 7-12, 1996
Vancouver, BC
Conference Secretariat,
XI International Conference on AIDS, PO Box 48740,
595 Burrard St., Vancouver,
BC, Canada V7X 1T8;
800/780-AIDS.

▲ Western States Pharmacy Conference
February 23-25, 1996
Breckenridge, CO
Contact: Western States Pharmacy Conference, 333 West Hampden Ave., Suite 1050,
Englewood, CO 80110;
303/761-8818.

▲ Winter Therapeutics Conference, 1996
February 25-28, 1996
Breckenridge, CO
Contact: UCHSC School of Pharmacy, Box C238,
4200 East Ninth Ave.,
Denver, CO 80262;
303/270-8645.

▲ Seventh National Meeting for State Cancer Pain Initiatives
April 11-14, 1996
Austin, TX
Contact: The Resource Center for State Cancer Pain Initiatives, 1300 University Ave.,
#3671, Madison, WI 53706;
608/265-4013.

▲ Subacute Care '96
May 14-16, 1996
Atlanta, GA
Contact: Subacute Care '96 Conference Registration Center, Dulles International Airport,
PO. Box 17413, Washington, DC 20041;
800/765-7616.

Upcoming conventions, conferences, symposia, and workshops of interest to managed care pharmacists are listed in JMCPs Events column. Listings are placed on a space available basis. Send notices to the editor at PO. Box 6565, Athens, GA 30604.

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INSTRUCTIONS FOR AUTHORS

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

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

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

MANUSCRIPT PREPARATION

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

*JMCP* abstracts should be structured using the following subheadings for the types of articles shown:

**Comparative Research**
- Objective
- Design
- Setting
- Patrons
- 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 six or less; when seven or more, list only the first three and add et al.)


2. No author given


3. Journal paginated by issue


4. Book or monograph by authors


5. Book or monograph with editor, compiler, or chairman as author


6. Chapter in a book


7. Government agency publication


8. Dissertation or thesis


9. Paper presented at a meeting


**SUBMISSION OF MANUSCRIPTS**

Four complete copies of the manuscript, including photocopies of figures, should be submitted to the *JMCP* Editor at P.O. Box 6565, Athens, GA 30604; 706/613-0100, 706/613-0200 (fax).

In a cover letter, the corresponding author should:

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

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

“In consideration of the Academy of Managed Care Pharmacy (AMCP) taking action and reviewing and editing this submission, the author(s) undersigned hereby transfer(s), assign(s), or otherwise convey(s) all copyright ownership to AMCP in the event that this work is published by AMCP.”

“I was an employee of the United States Government when this work was prepared for publication; it is therefore not protected by the Copyright Act, and there is no copyright that can be transferred.”

**References**


PROFICIENCY: Outcomes Research, Pharmacoeconomics and the Pharmaceutical Industry

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

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

INSTRUCTIONS
This quiz affords 1.0 hours (0.1 CEUs) of continuing pharmaceutical education in all states that recognize the American Council on Pharmaceutical Education. To receive credit, you must score at least 70% of your quiz answers correctly. To record an answer, darken the appropriate block below. Mail your completed answer sheet to: Academy of Managed Care Pharmacy, 1650 King Street, Suite 402, Alexandria, Virginia 22314. Assuming a score of 70% or more, a certificate of achievement will be mailed to you within 30 days. If you fail to achieve 70% on your first try, you will be allowed only one retake. The ACPE Provider Number for this lesson is 692-233-96-002. This offer of continuing education credits expires January 31, 1997.

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Date

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CONTINUING EDUCATION: OUTCOMES RESEARCH, PHARMACOECONOMICS AND THE PHARMACEUTICAL INDUSTRY

LEARNING OBJECTIVES

After studying this article, the reader should be able to:
1. Understand why almost all pharmaceutical companies have some type of pharmacoeconomic support.
2. Define the terms outcomes research and pharmacoeconomics.
3. Define the customers of pharmacoeconomic efforts of the pharmaceutical industry.
4. Understand how pharmacoeconomic and outcomes research is used to support a pharmaceutical manufacturer's product line.
5. Describe an organizational structure for the conduct of pharmacoeconomic studies within a pharmaceutical company.

SELF-ASSESSMENT QUESTIONS

For each item, select the one best answer and mark it on the answer sheet on page 48.

1. Reasons why the pharmaceutical industry is conducting pharmacoeconomic and outcomes research include all of the following except:
   a. To find new avenues for providing quality health care at lower cost.
   b. To demonstrate the safety and efficacy of their products for the FDA.
   c. To demonstrate the value of pharmaceuticals in health care systems.
   d. To demonstrate to employers what the health care dollar is buying.

2. Outcomes research is a segment of pharmacoeconomics.
   a. True.
   b. False.

3. The pharmaceutical industry is interested in pharmacoeconomic studies for which of the following reasons?
   a. To compare relative costs of treatment between countries.
   b. To assist key customers with needed information.
   c. To provide pricing information for drug products.
   d. All of the above alternatives are correct.

4. Outcomes research can be used to identify the most cost-effective way to manage a medical event between different regions within a health plan.
   a. True.
   b. False.

5. Which of the following customers of pharmacoeconomics and outcomes research is most important from the perspective of the pharmaceutical industry?
   a. FDA.
   b. Managed care organizations.
   c. Government (Medicare/Medicaid).
   d. Employees of Fortune 500 companies.

6. The following types of studies most commonly conducted by the pharmaceutical industry are used to meet the needs of the managed care customer except:
   a. Cost-minimization analysis.
   b. Cost-benefit analysis.
   c. Decision-analysis models.
   d. Prospective naturalistic studies.

7. Although clinical research is becoming more global within the pharmaceutical industry, outcomes research and pharmacoeconomics are not influenced by this trend.
   a. True.
   b. False.

8. Which of the following types of pharmacoeconomics studies always measure alternatives in monetary terms?
   b. Cost-benefit analyses.
   c. Quality of life comparisons.
   d. Cost-utilty analyses.

9. Pharmacoeconomic information is used by MCOs for:
   a. Price negotiations.
   b. Establishing clinical pathways.
   c. Financial analysis.
   d. All of the above alternatives are correct.

10. Which of the following types of pharmacoeconomic studies would not provide information to the pharmaceutical manufacturer at the time of a product launch?
    a. Phase III economic trials.
    b. Decision analysis models.
    c. Cost of care evaluations.
    d. Naturalistic prospective evaluations.

Demographic Information (not for scoring)

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

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

13. How many minutes did it take you to complete this program, including the quiz?
    Continued on page 65

See text of article beginning on page 48 of this issue of JMCPO. This article qualifies for 1.0 hours of continuing pharmaceutical education (0.1 CEUs). The Academy of Managed Care Pharmacy is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. This is program number 0942-054-002 in AMCP's educational offerings.

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