Janus Commission (AACP)

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INTRODUCTION

The Janus Commission was established by, 1995–96, AACP President Mary-Anne Koda-Kimble to scan the healthcare environment and to identify, analyze, and predict those changes within the environment likely to profoundly influence pharmacy practice, pharmaceutical education, and research, and to alert the academy to both threats and opportunities that such environmental changes present. The Commission took its name from the Roman god Janus, which had one head with two faces capable of looking in opposite directions at the same time.

HISTORY

The Commission chose to define "the environment" as encompassing the healthcare delivery system, health professions education, the academic health center and research enterprise, and the related social, economic, and political forces which impact these three areas. It has did so by recognizing that this did not constitute the entire environment which could be considered in such a discussion.

The Commission convened via face-to-face meetings and conference calls throughout 1996 and 1997 and extensively discussed several issues. Throughout its deliberations, the Commission was drawn repeatedly to the pervasive influence of a changing, more intensively integrated and managed healthcare system on both pharmaceutical education and pharmacy practice. This fundamental change in healthcare was the primary influence in the Commission's thinking and recommendations.

MISSION

The Commission believes that a revised model for pharmaceutical education is needed to meet the challenges presented by the changing healthcare system. In particular, schools and colleges of pharmacy must become true "activists" in healthcare policy, services delivery, and research in order to effectively achieve their missions in professional education. Employing the analogy of the pharmaceutical industry, the Commission suggests the following fundamental areas of emphasis for schools and colleges:

- The need for enhanced research and development activities related to the provision of, compensation for, and outcomes of pharmaceutical care.
- Sustained curricular reform efforts that ensure successful "manufacturing" of competent and caring pharmaceutical care providers.
- Aggressive "marketing" programs, working in collaboration with the profession of pharmacy, that promote the delivery of pharmaceutical care and foster enhanced practice/education partnerships.
- Enhanced interaction with the "product" of professional education programs—the pharmacist—to ensure that graduates can and will continue to provide effective clinical, humanistic, and economic outcomes in the course of their professional careers.

Finally drawing upon the previous works of the Pew Health Professions Commission and the AACP Commission to Implement Change in Pharmaceutical Education, the Janus Commission believes that fundamental actions must be taken immediately within the academy to ensure the future success of our professional programs and graduates within the evolving healthcare system. Among these are:

- Completion of the evolution of the "values system" of pharmaceutical education toward producing graduates who are patient-centered providers of pharmaceutical care.
- Active involvement by administrators and faculty of colleges and schools of pharmacy in healthcare sys-

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tem decision making, policy determinations, and research activities.
- Creation by colleges and schools of action-oriented business plans that result in effective partnerships with practice organizations and healthcare delivery systems.

The Commission encourages a thorough and critical reading of its report and looks forward to a very healthy, lively, and productive dialogue within the Academy.

APPENDIX

Members of the Janus Commission

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Joint Commission for the Accreditation of Health-Care Organizations

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INTRODUCTION

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is a private, voluntary, not-for-profit organization that serves as a gatekeeper for health care quality and safety. Currently, more than 19,000 health care organizations in the United States and many other countries are JCAHO accredited.[1] Since its earliest inceptions almost 50 years ago, JCAHO has striven to establish health care standards and performance measures. The mission of JCAHO is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

BACKGROUND

The organization takes its origins from a peer-to-peer-based practice starting first in the early 1900s with the American College of Surgeons, which established minimum hospital standards. The majority of early hospitals participating could not pass even these minimum standards. Ernest Codman, MD, is credited as the father of JCAHO. He proposed the end-result system of hospital standardization. Under this system, a hospital would track every patient long enough to determine whether the treatment was effective. If not effective, a determination would be made as to why not.

In 1951, the American College of Surgeons were joined by the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association to create JCAHO as it is known today. The Canadian Medical Association has since withdrawn from JCAHO;[1] however, they continue a process similiar to the current JCAHO. The governing body is made up of 28 members with a diverse background in health care, business, and public policy. Members include nurses, physicians, consumers, medical directors, administrators, providers, employers, labor representation, health plan leaders, quality experts, ethicists, health insurance administrators, and educators. Their role is to provide policy and leadership oversight.

Currently, JCAHO accredits the following types of organizations:

- General, psychiatric, children's, and rehabilitation hospitals.
- Health care networks, including health plans, integrated delivery networks, and preferred provider organizations.
- Home care, including infusion, home health, hospice, personal care and support, and home medical equipment.
- Nursing homes and long-term care, including long-term care pharmacies.
- Assisted living.
- Behavioral health, including mental health, chemical dependence, mental retardation, and foster care.
- Ambulatory care, including outpatient surgery centers, rehabilitation centers, infusion centers, group practices, and specialty centers, such as birthing centers, endoscopic centers, and pain centers.
- Clinical laboratories.

ACCREDITATION STATUS

Even though the accreditation process is voluntary, much emphasis is placed by health care organizations to successfully achieve accreditation status. Hospitals who receive federal funding from the Centers for Medicare and Medicaid Services, in particular, must adhere to the rigorous preparation and survey process. Because 80% of the approximate 5000 hospitals or health care systems receive federal funding, the JCAHO accreditation process, although voluntary, takes on a lot more meaning if the organization wants to continue to receive federal funds. The Social Security Amendment passed in 1965 granted

hospitals deemed status in the 1960s if they were JCAHO accredited. Organizations who were JCAHO accredited were deemed compliant with the Medicare Conditions of Participation for hospitals. Consequently, today the majority of hospital systems must participate in the JCAHO accreditation process and adhere to its standards.

The long-term care (LTC) accreditation process is actually the second oldest JCAHO program and has been accrediting LTCs since 1966.[1] More than 2800 organizations participate in this program. However, unlike hospitals, it has not received deemed status to date. Consequently, many skilled nursing home facilities continue to not opt for JCAHO accreditation to the same level as hospitals. Instead, they adhere to state licensing requirements alone. In the late 1990s, a resurged interest in the LTC accreditation process occurred precipitated by managed care's interest in JCAHO accreditation. Many managed care organizations were requiring JCAHO accreditation to service their patient population and LTC beds. However, the advent of the Prospective Payment System (PPS) in 1999, fueled by the balanced Budget Act of 1996, has more recently left a mixed signal as to the value and cost of being JCAHO accredited.

The home care accreditation program[2] is one of the more diverse processes. The reasons for the 6400 organizations to participate in accreditation are actually four separate and distinct submarkets: home infusion pharmaceuticals; home medical equipment; home health, personal care, and support; and hospice. Collectively, these entities are often referred to as alternate site. That is, alternate to hospitalization. First, the home infusion or home intravenous (IV) segment. As an organized form of health care delivery, home infusion has only been in use since the early 1980s. Early patients requiring home infusion services were generally those with chronic disease in which lifetime hospitalization was not an option (e.g., short gut syndrome requiring parenteral or enteral nutrition, hemophiliacs requiring factor VIII). The changes in the Medicare reimbursement structure or diagnosis-related groups (DRGs) in the mid-1980s had only an indirect impact on the growth in patients serviced in the home care setting because Medicare does not pay for prescription medications, including most IV medications in the outpatient or ambulatory setting. Mainly, the growth in home infusion occurred due to the financial pressures of managed care influences to release patients more quickly from the hospital when therapies were considered safe, yet required prolonged use of IV medications. For example, the use of IV antibiotics for the treatment of such conditions as osteomyelitis and other soft-tissue infections, such as cellulitis or status post-surgical infections. The human immunodeficiency syndrome epidemic of the late 1980s and early 1990s also fueled the growth in the home infusion industry. However, this industry's interest in the home care accreditation program that started in 1998 stemmed more from competitive marketing reasons and financial reasons more from the pressures of managed care and other third-party payers instead of federal funding. About this time, JCAHO changed its name from the Joint Commission on Hospital Accreditation to the Joint Commission on Healthcare Organizations, thus acknowledging the changing shape of health care delivery.

The home health agency or skilled visiting nurse component of home care also has diverse reasons to seek JCAHO accreditation. JCAHO received deemed status in 1993 for its Medicare-certified organizations. However, non-Medicare agencies also exist across the United States. In fact, not all states require agency licensing. However, the movement in the last decade has been for states to require agencies to be licensed. More often, similar marketing and financial motives to attract third-party payers have also fueled the motivation for non-Medicare home health agencies to seek JCAHO accreditation. However, the Balanced Budget Act of 1996 has had profound effects on home health agencies and forced the closure and consolidation of agencies as PPS took effect on October 1, 2000.

The hospice segment of home care usually has a federal funding component as well. JCAHO just received deemed status in 1999.[1] Originally, JCAHO had a separate accreditation program for hospice; however, the hospice standards have been folded into the home care standards manual.

Of this diverse segment of health care, home medical equipment (HME) is probably the most diverse group within this segment. Participants range from HME dealers with little to no clinical expertise providing ambulatory aids such as wheelchairs, walkers, and intense clinical services and equipment, such as clinical respiratory therapists providing oxygen, ventilators, and apnea monitors. Unlike hospitals and home health care that receive federal funds through Medicare part A benefits, HME receives federal payment through Medicare part B benefits. As of yet, deemed status or the requirement to be JCAHO accredited has not been a motivating factor for seeking accreditation in this market. However, there are some reports that it may be required in the future. Marketing and financial reasons from third-party payers and managed care predominantly have been the motivating force to voluntarily seek JCAHO accreditation. In addition, other healthcare organizations, such as hospitals and LTC facilities that are JCAHO accredited, require their vendors to be accredited. This exempts these HME organizations

from being included in the hospital, home health, or LTC organization's accreditation process.

With the changes in health care delivery, ambulatory care is also a growing segment of accreditation. Currently, more than 1000 centers are accredited. These include ambulatory surgery centers, community health centers, group medical practices, Native American health clinics, and other specialty centers. In addition, they received deemed status in 1996.[3]

ACCREDITATION PROCESS STANDARDS

When not motivated to participate for involuntary reasons such as the withholding of federal funding, most health care organizations find the JCAHO accreditation process to be an investment into risk management. Organizations agree to be measured against national standards set by health care professionals. No longer is the accreditation process a set of minimum standards. Once the standards emphasis were structural in nature. Structural standards assumed that care should be good because the opportunity existed for such, such as the right physical plant or the right number of staff. In 1987, the Agenda for Change was launched. Its emphasis is based on actual organizational performance and processes performed; that is, is the care provided actually safe and quality oriented? Organizations during the last 10 years have had to show that the care provided is in fact efficacious, efficient, cost effective, and safe. JCAHO has almost gone full circle with Dr. Codman's origin idea, except the current JCAHO process continues to be standards based, not just outcomes based. Organizations must show that access to care is timely, staff is oriented and competent, and sentinel events and complaints are incorporated into the organization's assessment processes.

However, JCAHO is also striving for a more continuous and data-driven process. The precursor to their ORYX Initiative or outcomes performance measurement was the IMS system first launched in 1988.[4] In 1998, hospitals and LTC facilities began to participate in the collection of outcomes data via select clinical measures and began to submit that data to JCAHO for analysis. Home care has followed suit in the year 2000. However, as of this writing, JCAHO is looking to modify its home care requirements for collecting outcomes data for ORYX.

The goal of the JCAHO accreditation process is that it will continue to be standards driven with an increased emphasis on continuous data. In the last few years, the JCAHO accreditation process—in particular, for hospitals—has been challenged. Payers continue to challenge the value of the accreditation process cost versus quality. As health care organizations continue to evolve, change, and consolidate, so must JCAHO evolve, change, and consolidate.

In 1999, the Board of Commissions established an Oversight Task Force for the Accreditation Process Improvement (API) Initiative. The purpose is to oversee the continuous improvement in the accreditation process.[1] The resulting changes are intended to enhance the evaluation of critical patient safety and patient care functions and to achieve an accreditation process that remains consultative and focused on performance improvement. A white paper was published outlining a future operational model that will continue to build and expand on technology, performance data, presurvey self-assessments, a fully automated interface with JCAHO, increased surveyor development, and a more continuous accreditation process. Instead of a once every 3 years site visit, two 18-month site visits would occur that evaluate select standards. In addition, since health care entities are so diverse, there is a desire to create a model that is more data driven, less predictable, and more customized to an individual organization.

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Joint Commission of Pharmacy Practitioners (JCPP)

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INTRODUCTION

Because of the diversity of practice locales and specialties found within pharmacy, there is no one professional association of which all pharmacists are members. The existence of multiple professional associations, each with its own unique focus, is an effective way to meet many of the professional needs of a highly differentiated practitioner population. However, it is important that these organizations have a means to collaborate effectively on major professional, regulatory, and legislative issues that confront pharmacy. The Joint Commission of Pharmacy Practitioners (JCPP) fulfills this need.

HISTORY

The JCPP was established in 1977 and serves as a discussion forum on matters of common interest and concern to the profession. As a discussion forum, JCPP facilitates effective representation of pharmacists on professional, educational, legislative, and regulatory issues. Although JCPP has no intrinsic authority to speak on behalf of its member organizations, discussions within the JCPP forum have identified many areas of agreement and have allowed participating organizations to adopt identical positions on a variety of professional issues. The significance of this is found in the fact that, collectively, the member organizations of JCPP represent virtually all pharmacy practitioners in all practice environments.

MEMBER ORGANIZATIONS

The membership of JCPP is not composed of individual pharmacists. Instead, JCPP's membership is composed of national pharmacy organizations who themselves represent either individual pharmacists or entities critical in some way to the practice of pharmacy (e.g., schools of pharmacy, state boards of pharmacy). The member organizations of JCPP are as follows:

Academy of Managed Care Pharmacy (AMCP)
100 N. Pitt Street, Suite 400, Alexandria, Virginia 22314; Phone: (703) 683-8416; Fax: (703) 683-8417; Judith A. Cahill, Executive Director.

American Association of Colleges of Pharmacy (AACP)
1426 Prince Street, Alexandria, Virginia 22314; Phone: (703) 739-2330; Fax: (703) 836-8982; Lucinda L. Maine, Executive Vice-President.

American College of Apothecaries (ACA)
2830 Summer Oaks Drive, Bartlett, Tennessee 38134; Phone: (901) 383-8119; Fax: (901) 383-8882; D.C. Huffman, Jr., Executive Vice-President.

American College of Clinical Pharmacy (ACCP)
3101 Broadway, Suite 650, Kansas City, Missouri 64111; Phone: (816) 531-2177; Fax: (816) 531-4990; Robert M. Elenbaas, Executive Director.

American Council on Pharmaceutical Education (ACPE)
20 N. Clark St., Suite 2500, Chicago, Illinois 60602; Phone: (312) 664-3575; Fax: (312) 664-4652; Peter H. Vlasses, Executive Director.

American Pharmaceutical Association (APhA)
2215 Constitution Avenue NW, Washington, DC 20037; Phone: (202) 628-4410; Fax: (202) 429-6300; John A. Gans, Executive Vice-President.

American Society of Consultant Pharmacists (ASCP)
1321 Duke Street, Alexandria, Virginia 22314; Phone: (703) 739-1300; Fax: (703) 739-1321; R. Timothy Webster, Executive Director.

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American Society of Health-System Pharmacists (ASHP)
7272 Wisconsin Avenue, Bethesda, Maryland 20814; Phone: (301) 657-3000; Fax: (301) 652-8278; Henri R. Manasse, Executive Vice-President.

National Association of Boards of Pharmacy (NABP)
700 Busse Highway, Park Ridge, Illinois 60068; Phone: (847) 698-6227; Fax: (847) 698-0124; Carmen A. Catizone, Executive Director.

National Community Pharmacists Association (NCPA)
205 Daingerfield Road, Alexandria, Virginia 22314; Phone: (703) 683-8200; Fax: (703) 683-3619; Bruce Roberts, Executive Vice-President.

National Council of State Pharmacy Association Executives (NCSPAE)
4041 Devlin Court, Tallahassee, Florida 32308; Phone: (850) 906-0779; Fax: (850) 893-1845; Steven E. Glass, Administrative Manager.

MAJOR PROGRAMS

JCPP meets four times each year, and those organizations whose membership is composed of individual pharmacy practitioners chair and host the meeting on a rotational basis (i.e., AMCP, ACA, ACCP, APhA, ASCP, ASHP, and NCPA). Participants in the quarterly meetings include the chief elected officers and staff of the member organizations.

One or more major topics for in-depth discussion are identified for each meeting. These topics represent issues confronting the profession at that point in time where there is value in exchanging information or seeking collaboration among the member organizations. These discussions may result in a consensus position among all eleven organizations, or allow those organizations who share a common point of view to identify each other and work collaboratively. Over the years, JCPP has facilitated collaboration among its member organizations on issues dealing with pharmacy education, practitioner licensure, professional and technical manpower, federal legislation or regulations, and programs developed by pharmaceutical companies that directly impact on pharmacy practice.

One initiative that is now organized and guided by JCPP is a series of strategic planning conferences for the profession—originally titled "Pharmacy in the twenty-first Century" (P-21). Although the first P-21 conference in 1984 was organized through other means,[1] JCPP was responsible for the P-21 conferences held in 1989 that focused on "Opportunities and Responsibilities in Pharmaceutical Care," and in 1994 that dealt with "The Changing Healthcare System: Implications for Pharmaceutical Care."[2,3] In 1999, with the imminent dawn of the twenty-first century, the P-21 moniker was dropped, and the conference was titled "Re-engineering the Medication Use System."[4]

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PROFESSIONAL DEVELOPMENT

Long-Term Care, Clinical Pharmacy Careers in

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INTRODUCTION

The role of the clinical pharmacist in long-term care, also called a consultant pharmacist, continues to expand with the recognition of drug-related problems that affect the quality of life of seniors. In addition to the potential adverse outcomes associated with medication-related problems, the cost of these problems is staggering. In fact, the total annual direct medical cost of medication-related problems in nursing homes exceeds $7 billion.[1]

ROLE OF CONSULTANT PHARMACISTS

Consultant pharmacists closely monitor each nursing home resident's medication regimen, monitoring for potential drug or disease interactions, dosing irregularities or side effects, and for medication use that may be considered inappropriate for the geriatric resident. This review is multifaceted and takes into account the information provided in the written medical record, as well as input from the staff, resident, and family. Various services are provided to the facility (Table 1). Inservice education programs are provided to the nursing staff and to family or resident meetings, if requested. Consultant pharmacists frequently participate on interdisciplinary care plan teams that focus on individual resident needs, such as fall risk assessment, weight loss evaluations, or pain management programs. Through ongoing monitoring of quality assurance programs, the consultant assists the facility in providing quality improvement for better resident care and in meeting state and federal regulations.

The success of consultant pharmacists' drug regimen reviews was reported in the Fleetwood study, which demonstrated that the reviews improved therapeutic outcomes by 43% and save as much as $3.6 billion annually in costs associated with medication-related problems.[2]

HISTORY

The concept of consultant pharmacy was first born in the early 1970s with the formation of the American Society of Consultant Pharmacists (ASCP), which has since also become known as America's Senior Care Pharmacists. About the same time, the centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) recognized the importance of medication management for the frail elderly in nursing homes, and in 1974, required that all medications for Medicare residents of nursing homes be reviewed on a monthly basis. In 1987, the requirement was amended so that all Medicare and Medicaid residents are required to have a monthly medication review by a pharmacist. In addition to the need for therapeutic drug monitoring, pharmacists recognized the need for unit dose packaging and specialized delivery services for nursing home residents in an effort to reduce medication errors and increase the efficiency of the systems.[3]

A pharmacy career in long-term care is typically associated with the provision of consultant pharmacy services to nursing home facilities. More recently, however, the opportunities for pharmacists in this practice setting have expanded far beyond the role of providing medications and medication reviews to only nursing homes.

Table 1 Types of consultant pharmacist services

- Drug regimen review
- Drug information
- Quality assurance programs
- Inservice education programs
- Therapeutic drug monitoring
- Patient counseling
- Pain management
- Interdisciplinary care planning
- Pharmaceutical care planning
- Pharmacokinetic dosing services
- Drug research programs

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Table 2 Job settings for consultant pharmacists

- Nursing facilities (skilled/intermediate care)
- Assisted living facilities/board and care homes
- Correctional institutions
- Hospitals (subacute/transitional care)
- Home health agencies
- Industry
- Mental institutions
- Alcohol or drug rehabilitation centers
- Mental retardation facilities
- Community health centers
- Retail pharmacies
- Health maintenance organizations
- Hospice
- Retirement communities
- Adult day care
- Physician offices
- Ambulatory care centers

(From Ref. [1].)

Terms such as consultant pharmacist and senior care pharmacist are used interchangeably to describe the type of pharmacist, rather than focusing on the physical setting. In addition to providing services for 1.8 million residents in more than 16,000 nursing homes in the United States, consultant pharmacists also provide medications and medication reviews for jails and prisons, home health agencies, and assisted living facilities, among others (Table 2).

TRAINING AND CERTIFICATION REQUIREMENTS

The usual training for a pharmacist in long-term care, or senior care, is a background or strong interest in providing care for the elderly. Beyond the pharmacy degree, there are now more than 800 certified geriatric pharmacists (CGPs) practicing in all areas of the world. The certification for recognition as a geriatric pharmacist first became available in 1997, and is administered by the Commission for Certification in Geriatric Pharmacy (CCGP). The CGP is not required for a career in long-term care pharmacy but is an asset for someone seeking a position in the field related to geriatric pharmacy. The CGP has demonstrated knowledge in the specific clinical areas that are required for the provision of consultant services to the elderly. In addition to educational training, the pharmacist must possess excellent verbal and written communication skills specific to the needs and considerations of the elderly. It is imperative to have the ability to work effectively with physicians, nurses, and other healthcare providers because the interdisciplinary approach is key to providing positive patient outcomes by improving the quality of life for residents in the variety of available long-term care settings. Postgraduate training programs, or short-term clinical rotations, are available in a variety of geriatric-related topics, including dementia, Alzheimer's disease, geropsychiatry, and Parkinson's disease, through the ASCP Research and Education Foundation.

PROFESSIONAL OUTLOOK

As mentioned previously, careers are not limited to those serving the elderly who reside in a nursing home. Some states require consultant pharmacist services in assisted living facilities. As the senior population continues to grow, so does the need for pharmacists trained specifically in the area of geriatrics.

Within the job settings, consultant pharmacists may be self-employed or work for a provider pharmacy. Provider services typically include the operation and management of the medication distribution system and consultant services typically refer to the clinical services. Some consultants provide only the consulting services and others provide consulting services, in addition to dispensing the medications.

Innovation has been the key word in the evolution of the practice of consultant practice in long-term care settings. Thus, it will continue to be a key to the future success of pharmacists willing to step out of the traditional pharmacy practice settings and provide much needed services to the growing senior population.

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PROFESSIONAL DEVELOPMENT

Managed Care, Clinical Pharmacy Careers in

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INTRODUCTION

When care is managed, health systems are accountable for providing high-quality clinical care, while balancing the economic factors, to deliver cost-efficient health outcomes.[1] The application of business practices to health care requires accountability for financial and clinical outcomes. Financial accountability is ensured by applying fixed reimbursement rates to the delivery of care and services. Reimbursement rates are set by the government [Centers for Medicare and Medicaid Services (CMS)], insurance companies, or health maintenance organizations (HMOs). Fixed reimbursement rates require that the delivery system or physician group provide care for their assigned patients at a set rate or premium. If the cost of managing assigned patients exceeds the reimbursement rate, the delivery system loses money. The system or group of physicians is at risk for, or capitated for, the management of their assigned patients.

Accountability for clinical outcomes is negotiated by managed care organizations with independent practice associations and preferred provider organizations (PPOs) for a discounted fee for service. Physician providers accept a discounted fee for services rendered and agree to abide by certain quality and utilization requirements in return for access to a defined membership group. Quality standards for medical care have been established by the National Committee for Quality Assurance (NCQA), whose mission it is to improve health care in the United States by providing information about the quality of care and service delivered by managed health care systems.[2] The Health Plan Employer Data and Information Set (HEDIS) measures focus on specific quality issues defined by NCQA and provides employers with standardized performance measures to compare managed care organizations. Representative NCQA/HEDIS measures include the use of appropriate medications in asthma, chlamydia screening in women, controlling high blood pressure, beta-blocker treatment post myocardial infarction, and antidepressant medication management. Employers evaluate plans based on these medical quality indicators, as well as effectiveness of care, use of services, cost of care, informed health care choices, and health plan stability.

Managed care applies to a wide range of settings including HMOs, PPOs, integrated delivery systems (IDSs), physician hospital organizations (PHOs), and point-of-service plans.

CAREER CHOICES AND SETTINGS

Managed care has penetrated most geographic areas within the United States and essentially all health care settings. As a result, career opportunities for clinical pharmacists are vast and diverse. While previously pharmacists interested in managed care positions were limited to settings such as pharmacy benefit management (PBM) companies or insurance companies, career opportunities in managed care have expanded and are available in hospitals, clinics, and private practices in both urban and rural areas.

Traditional managed care pharmacy roles were those that placed the pharmacist in the PBM or insurance company setting to provide administrative, formulary management, prescription claims management, and contracting services. With increasing managed care penetration, IDSs, physician practices, PPOs, PHOs, and HMOs are hiring pharmacists to provide clinical services involving both quality of care and utilization management functions. Representative pharmacy opportunities in managed care are outlined in Table 1.

PREPARING FOR A CLINICAL PHARMACY CAREER IN MANAGED CARE

Managed care needs qualified clinical and financial pharmacy managers, grounded in solid business principles and clinical pharmacy skills. The doctor of pharmacy degree is strongly desired in pharmacists who graduated prior to 1995, and mandatory for recent graduates. Depending on the position focus, advanced training in pharmacoeconomics or managed care as either a 1-year residency or 2-year fellowship is recommended. Doctor

Table 1 Clinical pharmacy careers in managed care

Role	Typical settings[a]	Typical functions	Typical prerequisites[a]
Retail network manager	HMO PBM	Contracting with retail pharmacies Audit and compliance functions Pharmacy reimbursement	Pharmacy degree Retail experience Business background
Claims manager	HMO PBM	Processing prior authorizations Developing criteria for new drugs	Pharmacy degree Managed care experience
Account manager	HMO PBM Drug company	Managing each business ventures Tracking financial performance Marketing new programs	MBA Pharmacy degree
Quality initiatives manager	HMO PBM IDS	Compliance programs for NCQA/HEDIS Coordinating data management	PharmD
Clinical specialist	HMO IDS PPO PHO PBM Drug company	Drug expert functions for providers, members, and formulary functions	PharmD Res
Data/population manager	HMO PBM Employer	Management and analysis of data for quality and cost-reduction initiatives	PharmD Res or Fel Pharmacoeconomics
Group practice pharmacist	PPO PHO IDS HMO	Managing the group's patient population and pharmacy costs	PharmD
Formulary manager	HMO IDS PBM	Identifying new strategies to manage drug entries, formulary reviews, and process	PharmD
Manager of clinical initiatives	HMO PBM IDS Employer	Design and implement cost-reduction and quality initiatives	PharmD
Utilization/case manager	IDS HMO	Manage high-risk populations as part of a team	PharmD
New business developer	HMO PBM	Identifies new client opportunities and develops business plans	MBA Pharmacy degree
Contracting	PBM HMO IDS	Contracts with drug companies, pharmacy providers, and/or physician's providers for services and drugs	Pharmacy degree MBA
Call center pharmacist	PBM IDS HMO.com	Provide telepharmacy services to patients and providers Compliance programs	Pharmacy degree
Home care pharmacist	IDS HMO	Prepare, deliver, administer, and monitor intravenous and enteral nutrition or drug products to patients in their homes	Pharmacy degree
Outcomes researcher	IDS HMO PBM	Measure the value of therapeutic interventions on the quality of life	Pharmacy degree Fel PhD or PharmD
Drug information specialist	IDS PBM	Research and develop answers to questions related to drugs and drug policy	Pharmacy degree Res
Information technology/ database manager	IDS HMO PBM	Integrate and manage database functions, informatics, and technology	Pharmacy degree

(Continued)

Table 1 Clinical pharmacy careers in managed care (*Continued*)

Role	Typical settings[a]	Typical functions	Typical prerequisites[a]
Outpatient pharmacist	IDS HMO	Counseling and dispensing medications Reinforce compliance and disease management programs	Pharmacy degree Res
Direct patient care	IDS PHO PPO	Condition/disease-focused clinics	PharmD Res Board certification

[a]Employer group, Employer; HMO, health maintenance organization; PPO, physician provider organization; PHO, physician hospital organization; IPA, independent practice association; IDS, integrated delivery system; PBM, pharmacy benefit manager organization; Res, residency training; Fel, fellowship training;.com, Internet commerce sites for medications.

of pharmacy students interested in a managed care career should pursue external rotations in progressive managed care settings. Experience with claims and benefit management, formulary management, disease management, quality certification, and large relational databases is very important. Pharmacists interested in account management may benefit from formal training in business administration and finance. Table 1 summarizes career opportunities that may require advanced training as a prerequisite.

Desirable skills and knowledge are summarized in Table 2. In addition to academic training, managed care pharmacists are called to respond to a rapidly changing, often unstable financial and clinical environment. Individual behavioral characteristics that are helpful in these circumstances may include flexibility and ease of response to change, open-mindedness, "pioneerism," and respect for the sense of urgency surrounding health care business evolution. Many managed care organizations are willing to hire pharmacists with desirable behavioral and clinical characteristics, realizing that knowledge related specifically to managed care practice can be acquired. Large organizations, whether managed care organizations, HMOs, IDSs, or PBM firms, are often willing to provide on-the-job training to advance pharmacists' skills in managed care. However, prospective employers may preferentially select candidates with previous managed care experience, thus underscoring the importance of selecting elective rotations in managed care settings.

Table 2 Desirable skills, knowledge, and behaviors of clinical pharmacists in managed care

Problem-solving skills
Exemplary oral and written communication skills
Knowledge of population management and pharmacoeconomic principles
Facility with large relational databases and information systems
Business and financial expertise
Comfort with the measurement science
Solid clinical skills, knowledge, and behaviors
A sense of urgency
Comfort in rapidly changing, unstable environments
Motivated by challenge
Teamwork
Interpersonal skills

PROFESSIONAL GROWTH IN MANAGED CARE PHARMACY

Many opportunities exist for career growth in managed care practice settings, just as they do in other practice environments. New graduates can usually qualify for staff pharmacist careers in benefit design, clinical, data analyst, or case management positions. Advancement can follow experience at entry-level positions, with or without advanced skills enhancement through external degrees or training programs. Much of the management of pharmacy benefits, irrespective of the site of practice, is science and can be learned didactically. However, a significant component of success in a managed care pharmacy career, like other pharmacy career paths, depends on facility with the art of the application of managed care skills, knowledge, and strategies—the so-called "craft" of the managed care pharmacist. The development of "craft" skills requires experience through application, which can only be learned during practice. Entry-level pharmacists may move on to clinical manager or team leader positions, or transition into higher business or administrative positions.

A parallel track is available within PBM companies for pharmacists with retail pharmacy experience. Pharmacy network management and contracting have be-

come important mechanisms for managing costs and enhancing revenue to health plans and PBMs. Retail pharmacy experience and business skills are desirable characteristics for pharmacists desiring advancement in the more traditional roles of pharmacists within managed care organizations.

Board certification and other postgraduate credentials may be useful to individuals, depending on their practice setting. However, in general, these credentials have not attained widespread acceptance as prerequisites for advancement within managed care organizations. The paucity of qualified individuals to deliver exemplary pharmacotherapy services, while balancing business and financial prerequisites has led to a limited candidate pool for managed care pharmacy positions. Over time, as a greater number of pharmacists enter and advance in managed care clinical pharmacy careers, board certification, certificate programs, and association affiliations or recognition may become more important delineators of high-quality pharmacists. In the interim, it is more important that pharmacists gain experience in the field and determine their compatibility with a career in managed care.

Managed care pharmacists are moving up the ranks within their organizations. In a survey conducted among 200 managed care pharmacists in 1997, the five most frequent job titles were director of pharmacy, regional director of pharmacy, pharmacy manager, vice president of pharmacy, and director of pharmaceutical division.[3] Many clinical pharmacists report directly to vice presidents or chief executive officers within their organizations.

CASE STUDIES OF CLINICAL PHARMACY PRACTICE IN MANAGED CARE

Hospice

Hospice services are often offered as part of an IDS or managed care organization. Typically, when patients and their families determine that end-of-life measures are indicated, they search for options to make the patient maximally comfortable, with appropriate care, and at an affordable cost. Hospice care can be offered as a purchased service or a covered benefit. In most cases, hospice care is capitated and must operate within a budget or lose money.[4] Pharmacists practicing in hospice settings may be called on to optimize rational pharmacotherapy and help to discontinue medications deemed no longer necessary for patient comfort. In this regard, the pharmacist and the rest of the patient's care team are managing care within a capitated limit.

All-Inclusive Care for the Elderly (PACE) Programs

There are several PACE programs across the United States that serve as day care and/or home care opportunities for elderly patients, referred to as participants.[5] PACE programs offer an alternative to nursing home placement, enabling frail elderly people to remain independent in their homes within the community. When elders enroll in a PACE program, their care becomes the responsibility of the program. PACE programs are funded through medicare and medicaid. The PACE program is responsible for provision of both drug therapy and medical care. Pharmacists can serve an important role in optimizing and simplifying drug therapy, at lowest cost. Given that many of the participants are seniors with multiple concurrent medications, careful individualization of dose is essential to minimize adverse events.

Utilization Management

Clinical pharmacists have been redeployed in ambulatory managed care settings to work with primary care providers to enhance both the quality and cost effectiveness of care delivered.[3,6] They are highly integrated within the system of care delivery. Population management strategies are used to identify the high-cost or low-quality providers with the greatest need for pharmacy care management. Provider profiles are used to continuously provide feedback to physicians, identifying cost-reduction and quality improvement opportunities. Clinical pharmacists can work with individual physicians or groups, such as a PPO or PHO, to ensure that the highest quality of care is provided within the capitation limits of the plan or group. Improvements in quality are accomplished through the pharmacists'' role in the development of clinical guidelines and pathways, while helping physicians understand the patients'' pharmacy benefits. Pharmacists may also work with individual high-risk patients to streamline drug therapy, decrease cost, and improve patient medication safety.

Specialty Clinics

In managed care, it is often a small percentage of patients (approximately 20%) who are responsible for the majority of the cost (80%)—often referred to as the 80/20 rule. It has been shown to be cost effective to manage these high-risk patients in specialty clinics or programs. Disease management programs offer many patients with specific conditions, enhanced management strategies to improve

the likelihood that they will achieve desired therapeutic outcomes as outpatients. Managed care organizations typically offer disease management programs in diabetes, asthma, depression, and other conditions in which the quality of follow-up and intervention has been shown to vastly improve patient outcomes, such as anticoagulation. In addition, specialty clinics are an approach to improving the management of patients with specific disorders, such as asthma, hypertension, and dyslipidemias.[7] Pharmacists may provide individualized care or participate as team members for case management or disease management of high-risk patients.

CONCLUSION

There are numerous opportunities for clinical pharmacists to contribute to high-quality patient care, business results, and drug benefit administration in a wide variety of managed care settings. Pharmacists are no longer limited to a narrow range of managed care opportunities within PBMs. Managed care settings offer intensity and challenge for clinical pharmacists with opportunity for upward mobility and career growth.

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PROFESSIONAL DEVELOPMENT

Managed Care Pharmacy Practice

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INTRODUCTION

Health system integration has been a dominant phenomenon since the early 1980s, and the trend is likely to continue. Understanding health system integration and its impact on pharmacy practice is challenging for many reasons, one of which is the continued rapid pace of change.[1]

Responding to the challenges of system integration is also complicated by the various types of organizations that are characterized as integrated health systems. In broad terms, an integrated health system is one that brings together hospital, medical, pharmaceutical, and other health services into a single organization and thereby offers the prospect of lower cost, an improved and more consistent quality of care, and greater marketing power. Managed care organizations (MCOs), such as health maintenance organizations (HMOs), preferred provider organizations (PPOs), and independent practice associations (IPAs), are considered integrated health systems because they manage healthcare services for a defined population, even though they may not be fully vertically integrated.[2]

Regardless of their size, structure, or service mix, integrated health systems have the same goal: to deliver high-quality care to a defined population at a competitive cost. If desired patient outcomes and standards of fiscal performance are to be achieved, pharmaceutical care must be delivered efficiently and consistently, and drug products must be used appropriately.[3] This is where the clinical pharmacist plays a crucial role.

The growth of managed care in the United States has fostered new and innovative roles for pharmacists in this area, such as consulting, disease management, wellness program development, technology assessment, and outcomes research. The skills necessary for these roles include communication and mediation, assertiveness, assimilation of drug information, evaluation of clinical and economic data, and the ability to work in teams. Demonstrating and documenting the value of these roles will be essential to the future of the profession of pharmacy.[4] As in many other areas of pharmacy, there is currently a tremendous demand for well-qualified clinical pharmacists in managed care settings.

OPPORTUNITIES AVAILABLE IN MANAGED CARE FOR CLINICAL PHARMACISTS

Core Strengths of Pharmacy

Managed care pharmacists have identified the following core strengths that pharmacists should have to enable them to thrive in a managed care setting. Pharmacists should:

- Have an established reputation and competency as drug therapy experts.
- Have established skills in automation and computer technology.
- Have a demonstrated understanding of, and appreciation for, quantitative and qualitative information.
- Be committed to helping patients.
- Be accessible to patients.
- Be focused on drugs and knowledge related to medications.
- Be experienced in adapting skills for surviving in a changing healthcare environment.
- Possess a wealth of online information and databases.
- Possess a strong clinical knowledge base and training that can support case management.
- Be experienced in applying data to business applications.
- Have access to automated dispensing technologies, which have increased pharmacy's capacity to take on additional responsibilities.
- Have good organizational skills.
- Possess leadership skills and be passionate about furthering the success of the profession.

Essential Skills

The changing marketplace and different patient needs are creating innovative roles for pharmacists in integrated

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health systems. However, unique skills are necessary for effectiveness in managed care; some of these skills will require additional training and education. Also, a different attitude is essential; for example, pharmacists must be willing to take risks and accept new responsibilities—ones that may be unlike those of a traditional position.[5]

There are certain skills that clinical and dispensing positions have in the managed care setting. These include drug information knowledge, communication and mediation skills, assertiveness, and the ability to work in teams.

Drug information knowledge

The trends that are occurring in managed care are those of disease state management, outcomes, wellness program emphasis, technology, and pharmacoeconomics. The important role of the pharmacist with regard to drug information is to assimilate and combine information with other components for use in the decision-making processes. These include not only patient-specific decisions, but also formulary decisions, for the entire managed population.

Pharmacists have the specific background to make the appropriate recommendations for product selection; however, is no longer the product's pharmacologic advantage over other medications the only factor in selection. Pharmacoeconomics and population characteristics, as well as many other factors, must be considered.[6]

Other essential skills for pharmacists in managed care include the following.

Communication and mediation skills

Understanding what other healthcare team members are looking for and communicating effectively is vital. As pharmacists increase their involvement in direct patient care, interacting with patients will require the ability to present information in terms that the patient will understand. With respect to being a mediator, the goals of cost containment must be clearly understood and accepted by all parties in order for success to be achieved; this responsibility often falls to the pharmacist.

Assertiveness

Healthcare and pharmacy are not exempt from market pressures, and pharmacists must accept the fact that, unless they assert their role and importance in the services that they offer, they may not be needed.

Ability to work in teams

The pharmacist must understand role definitions, develop empathy for other team members, and acquire the skills necessary to surpass expectations.[7] Team relationships are essentially balancing acts that can be upset easily if someone does not understand the practice philosophy or the role definitions within the team.

Innovative positions

Managed care systems offer innovative pharmacy practice positions in such areas as pharmacoeconomics, disease state management, outcomes research, wellness program management, and technology assessment. For individuals willing to expand their pharmacy practice and develop new skills, these positions can offer unique opportunities and growth.

Care coordinators and clinic coordinators

Some organizations have created interdisciplinary rounding teams for inpatient care. The responsibility for coordinating the transition from hospital to ambulatory care is delegated to these teams. For example, pharmacists from the HMO's home IV service attend rounds within the contract hospitals, focusing on monitoring drug therapy with respect to quality and cost effectiveness and facilitating a smooth transition from hospital to home care.

Many MCOs are using pharmacists to influence physician prescribing and to conduct clinics promoting appropriate use of pharmaceuticals. In addition, these pharmacists participate in direct patient care activities that relate to drug therapy, such as ordering and monitoring laboratory tests and providing effective patient follow-up to ensure patient satisfaction and high-quality care. Many of the pharmacist-coordinated clinics providing this patient care have been shown to improve patient outcomes and satisfaction and to support the efficient provision of services from other members of the healthcare team.[8]

Disease management and the patient

Disease management has been defined as quantifying, tracking, and controlling the unique set of cost drivers in any disease and the interactions of these drivers over the course of the disease across all elements of the healthcare system.[9] Studying the distribution and effects of medications in populations (pharmacoepidemiology), as well as the costs and comparisons of alternative courses of

therapy (pharmacoeconomics), helps determine where disease management can change practice the most.[10] These conditions are generally the most common, expensive, and treatable (e.g., asthma, diabetes, peptic ulcer disease, depression, cardiovascular disease) and provide the greatest opportunity for economic savings when disease management programs focus on them.[11]

Disease management requires that pharmacists add a number of skills to their professional role. These skills include managing information systems to collect and organize data, total quality management to improve processes, teamwork with patients and other professionals, budgeting to obtain compensation, teaching clinical care and appropriate drug use, and the ability to help move pharmacy from compartmentalized care to integrated care.[12] Most models of disease management use the pharmacist in a clinical role that goes beyond dispensing. Pharmacists are ideally qualified to participate in disease management because of their knowledge of drug therapy, communication, computer applications, and marketing, as well as sales, finance, and basic wellness issues. Pharmacists have a great opportunity in these situations, given their ability to communicate complex concepts in easily understood terms to help employee groups take advantage of disease management options.[13]

In the future, as healthcare systems make the transition from stage 1 (primarily fee for service) to stage 4 (primarily capitation), opportunities for disease management will increase.[14] For many MCOs, shifting from formulary management to disease management will be a means of improving the overall quality of care, reducing costs, and expanding patient involvement in care.[15] Decisions will not be based on individual components of care, such as the cost of drugs or other treatments; rather, a disease will be viewed in its entirety. As customized cost-management techniques are applied to each disease and patient, the pharmacist will assume a greater role in, and responsibility for, patient outcomes.[16]

Managing health

Wellness programs have been described as the community outreach component of disease management. These programs can link with disease management programs to provide follow-up support.

Pharmacists are ideally positioned to play a major role in wellness programs. Combining their outstanding clinical skills acquired during formal education, internships, externships, and work experiences with significant transferable skills, especially communication and interpersonal skills, makes pharmacists ideal candidates for counseling patients and producing the outcome of better overall healthcare at lower costs. Application of principles of disease prevention and management in individual or group counseling sessions can help patients learn how to care for themselves properly, thus reducing healthcare costs and improving their quality of life.[17]

In the future, wellness programs will most likely be a joint effort among payers, employers, patients, and providers. In these programs, pharmacists could serve as coordinators to ensure appropriate utilization of resources, effective communication, and optimal patient outcomes.[18]

Evaluating clinical and economic data

The focus on disease state management and outcomes will require that data on a patient's drug therapy be accessible to both hospital and ambulatory care providers. The pharmacist can play an integral role in the coordination and dissemination of these data. For example, institutional pharmacists will need to establish communication links with pharmacy providers in other settings to ensure optimal and seamless care.[19]

Pharmacists can provide a valuable service in evaluating the data resulting from treatments and helping patients make the most of their prescribed therapies.[20] A pharmacist could help select the appropriate formulary drug within a drug class and then teach the patient how to take the medication correctly.

Pharmacists also have a role as pharmacoeconomic analysts in comparing medications. Sometimes the investment in a more expensive medication reduces other costs to the HMO, but the data must be collected and tracked for these assumptions to be proved. To perform these analyses successfully, the pharmacist must be able to evaluate and interpret statistics and research articles. A sound understanding of pharmacoeconomic principles is also essential.

As more information about a given treatment is received, the pharmacist must always be prepared to perform the analysis again and incorporate the new information. Depending on new research or changes in the HMO-covered population and its needs, the pharmacoeconomic evaluation may lead to different results at a later date.

Because of the financial pressures to reduce healthcare costs without compromising quality, the pharmacist must have the ability to apply basic quantitative skills to evaluate options and then to blend those results with qualitative information to make decisions and recommendations.[21] Pharmacists will have to work directly with prescribers, helping them interpret and use phar-

macy claims data to achieve the best patient outcomes. Having a basic understanding of business and knowing when to seek additional information are increasingly necessary to operate successfully within the managed care environment.

Measuring outcomes

Measuring outcomes shifts the emphasis from products to patient results, which could eliminate the need for formularies.[22] Simply put, outcomes measurements evaluate systems and decide what works and what does not.

Healthcare providers are increasingly relying on pharmacists to perform outcomes research and quality-of-life studies. Pharmacists can apply basic quantitative skills in evaluating options and combine the results with qualitative information to make decisions and recommendations. For disease state management programs, measuring outcomes can be the key to success.[23]

As health delivery systems move toward total managed care, the need for outcomes studies will increase.[24] Issues to be addressed by outcomes research will include clinical efficacy of interventions, health-related quality of life, patient satisfaction, employee productivity, and resource utilization. Pharmacists can either participate in or direct outcomes research. Outcomes studies may also be used to support a pharmacy position for interventions.

Outcomes research must always be patient focused and useful for improving patient care. Many pharmacists already have the data to do their own outcomes research. Questions about appropriate prescribing and compliance can be answered by using pharmacy claims data. That information could be a tool in providing positive feedback to the patient, as well as to the prescriber.

MODEL CLINICAL PRACTICES IN MANAGED CARE

The American Society of Health-System Pharmacists (ASHP) and the Academy of Managed Care Pharmacists developed the *Accreditation Standard and Learning Objectives for Residency Training in Managed Care Pharmacy Practice* in 1997. This standard outlines specific requirements and principles that managed care pharmacies should have in place for training residents. The relevant practice areas include direct patient care, drug information, population-based pharmaceutical care, business administration and management activities, and practice management. Regular accreditation surveys and visits ensure that each site maintains the practice standards. The *Managed Care Pharmacy Practice Standard* can be found on the ASHP web site.[25]

In addition to the *Accreditation Standard and Learning Objectives for Residency Training in Managed Care Pharmacy Practice*, ASHP has published the following standards and guidelines, which provide guidance on model clinical practices to managed care pharmacies. (Note: The citations provided are from the *American Journal of Health-System Pharmacy*, but each of these standards or guidelines can also be located on ASHP's web site.[36])

- *ASHP Guidelines on Pharmaceutical Services for Ambulatory Patients.*[26]
- *ASHP Guidelines: Minimum Standard for Pharmacies in Institutions.*[27]
- *ASHP Guidelines on a Standardized Method for Pharmaceutical Care.*[28]
- *ASHP Guidelines for Obtaining Authorization for Documenting Pharmaceutical Care in Patient Medical Records.*[29]
- *ASHP Statement on the Pharmacist's Responsibility for Distribution and Control of Drug Products.*[30]
- *ASHP Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices.*[31]
- *ASHP Technical Assistance Bulletin on Drug Formularies.*[32]
- *ASHP Technical Assistance Bulletin on the Evaluation of Drugs for Formularies.*[33]
- *ASHP Guidelines on Medication-Use Evaluation.*[34]
- *ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting.*[35]

Other organizations that provide guidance on model clinical practices are those that measure pharmacy quality and utilization in the managed care area. The primary organizations are as follows:

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—JCAHO began providing accreditation services by focusing on hospitals; more recently, its services have been expanded to provide accreditation services for a wide continuum of healthcare providers. In fact, JCAHO shifted its accreditation focus toward a continuous quality improvement (CQI) process and incorporated outcomes measures into the standards. Information on JCAHO and its standards can be found at www.jcaho.org.

The National Committee for Quality Assurance (NCQA)—NCQA was founded in 1979, in an effort to establish a comprehensive quality measurement process

for MCOs. The focus of the NCQA accreditation process is the effective implementation of a CQI process into the medical services provided by the managed care organization. Information on NCQA and its standards can be found at www.ncqa.org.

The Health Plan Employer Data and Information Set (HEDIS)—The HEDIS reporting system is a series of specific performance measures designed to provide healthcare consumers with the information they need to reliably compare MCOs. HEDIS measures are self-reported by participating MCOs on a quarterly basis. Information on HEDIS, which is a joint project with NCQA, can be found at www.ncqa.org/pages/programs/hedis.

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Professional Networking Opportunities

There are many professional networking opportunities for clinical pharmacists who practice in the managed care setting. Some of the more prominent organizations include the following:

- The American Society of Health-System Pharmacists Center on Managed Care Pharmacy (www.ashp.org).
- The American Association of Health Plans (www.aahp.org).
- The American Medical Informatics Association (www.amia.org).
- The American Telemedicine Association (www.atmeda.org).
- The Academy of Managed Care Pharmacy (www.amcp.org).
- The National Business Coalition on Health (www.nbch.org).
- SCRIPT (http://scriptproject.org).

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Medicaid and Medicare Pharmaceutical Programs

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INTRODUCTION

There are two major government supported healthcare programs in the United States today. They are completely different in structure, purpose, and financing. One is Medicaid, which is operated by the state governments with financial support from the federal government. This support varies but is generally in the range of 53–80% of total expenditures, depending upon the state's per capita income. Medicaid is Title 19 of the Social Security laws and was enacted in 1965. It is intended for medically indigent persons. Such low-income persons must pass a means test of income and wealth maximum criteria. In 1998, about 40.6 million persons received benefits at an expense of $142 billion. Medicaid can be seen as a welfare program to replace the very different programs operated by states and counties before 1965, which had different eligibility criteria, benefit structures, and waiting/residency requirements impacting persons who moved residences. In essence, it standardized welfare programs.[1]

Medicare, on the other hand, was established also in 1965 to provide assistance for medical expenses for the aged and disabled. It is not a welfare program, but rather an insurance program, as beneficiaries have their premiums deducted from their monthly social security checks. All persons 65 years of age and above are eligible for hospital insurance (called Part A). Part B is a supplemental health insurance plan covering physician's and surgeon's fees, laboratory work, and other outpatient services. In 2000, 39.33 million persons were enrolled in Part A and 37.4 million of these were enrolled in Part B. This is an insurance program funded by enrollee payments of about $50.00 per month. Part A is funded by a tax on incomes of all persons of 7.65%.[2] Medicare is operated directly by the federal government through the Social Security Administration.

The role of drugs and pharmaceutical services could not be any different. In Medicaid, every state program has an outpatient drug benefit that covers virtually all prescription and OTC drugs available in the United States. There are some differences among the states, which will be discussed later. However, there has never been an outpatient drug benefit in Medicare. It has been discussed, and legislative initiatives have been planned, but it has not been brought to fruition in the 35-year history of the program. Medicare covers drugs used while a patient is hospitalized. Estimates of the likely cost of such an outpatient program are massive, and there is controversy as to the need.

MEDICARE: DESCRIPTION AND CONTACT POINTS

Medicare *is the health insurance program for people 65 years of age or older, certain younger individuals with disabilities, and citizens with End-Stage Renal Disease (permanent kidney failure with dialysis or a transplant, sometimes called ESRD).* This program is administered by the Department of Health and Human Services through the Health Care Financing Administration (HCFA) of the United States federal government.

- Contact with HCFA can be accomplished over the Internet at: http://www.hcfa.gov or http://www.medicare.gov.
- Via the telephone by calling: 1-800-Medicare (1-800-633-4227).
- Or by mailing the Medicare agency at: U.S. Department of Health and Human Services; Health Care Financing Administration; 7500 Security Boulevard; Baltimore, Maryland 21244-1850.

History

The quest for universal healthcare in the United States started during the depths of the great depression in the 1930s. President Franklin D. Roosevelt wanted it, however, American medicine vehemently opposed it. From that point, the protagonists and antagonists have been fighting the battle. The goal appeared to be in reach numerous times during the last 70 years; however, an inci-

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dent always came along to derail comprehensive reform. In 1965, the "Great Society" under President Lyndon B. Johnson moved forward with legislation providing a level of care for the elderly (Medicare). Medicaid was also enacted at the same time to cover low-income aged, blind, and disabled individuals, and parents and their dependent children on welfare. Piecemeal health coverage for select populations was continuing, and comprehensive reform was thwarted. These two federally initiated health proposals did not include mandatory ambulatory drug coverage. In 1988, the Medicare Catastrophic Act was signed into law by President Ronald W. Reagan and promptly vetoed by President George H. W. Bush before it could be implemented. This legislation would have provided a prescription drug benefit and a cap on patient liability. The law was rescinded, because high-income elderly felt they would pay more in premiums than they would receive in benefits.[3]

The passage of the Omnibus Budget Reconciliation Act (OBRA) of 1990 provided poor seniors who qualified for Medicare and Medicaid a level of mandatory patient care provided by pharmacists in addition to Medicaid prescription coverage.

The 1990s witnessed the creation of optional nonfederal prescription benefits for Medicare beneficiaries enrolled in Health Maintenance Organizations (HMOs), and in 1997, Medicare+Choice was established by President William J. Clinton which created numerous choices for recipients. The start of this millennium has witnessed the commitment of President George W. Bush to create a prescription benefit program for the elderly. This program could take several different paths. There could be comprehensive Medicare reform with prescription coverage and pharmaceutical care becoming a mandatory or optional benefit. There could also be just a prescription benefit passed for categorically defined individuals. Another option could be a block grant program enabling states to receive federal funds. States could have the flexibility in choosing to establish a drug benefit or enhance pharmaceutical coverage with existing voluntary plans. Failure of a political consensus among the President, Congress, the pharmaceutical industry, pharmacies, and patients could result in no additional prescription and pharmaceutical care coverage for consumers, at least until the next presidential election in 2004.

The Medicare Program

The basic Medicare insurance program, which provides benefits to consumers who are 65 or older, consists of two components.

The hospital portion is "Part A." It receives its name from the fact that it is "Part A" of Title XVIII of the Social Security Act.[4] This section of the legislation covers inpatient hospitalization, critical access hospitals, skilled nursing facilities, hospice care, and limited home healthcare.[5] Critical access hospitals are small facilities that provide limited outpatient care and inpatient services to individuals in rural areas.

Most people pay for "Part A" during their working years. They therefore receive this insurance benefit automatically when the appropriate time comes. Employees and employers each pay 1.45% tax on all wages and salaries.

The medical portion is "Part B," and it is included in the legislation as "Part B" of Title XVIII. It covers medical services including physician care, outpatient hospitalization services, and selected medical activities not covered in "Part A," such as occupational and physical therapists. This section will pay for diabetic supplies when medically necessary.

The cost to the Medicare patient changes each year. During the year 2001, it was $50.00 per month. This charge is deducted from the recipients' monthly Social Security check before it is received. The premiums paid by participants represent 25% of the program's cost. The remaining 75% is paid directly by a federal budget appropriation.

Healthcare Coverage Options

Eligibility for Medicare enables individuals to select one of a myriad of choices for receiving care.

The Original Medicare Plan

The first Medicare health insurance is now called the "Original Medicare Plan."[6] This is a fee-for-service plan. The provider charges a fee to the patient and or the government each time the service is provided. This arrangement is offered nationwide.

The federal government has authorized supplemental insurance polices to aid in paying for services not covered in the Original Medicare Plan. Up to ten supplemental plans can be marketed by private insurance carriers. These plans must be labeled "Medicare Supplement Insurance." There are high-cost and lower-cost policies. They differ in the scope of coverage, deductibles, and copayments. Several of these optional programs have limited outpatient prescription coverage. In addition to these supplements that are also called Medigap policies, the standardized benefits may also be sold as "Medicare Select" policies. The Medicare Select benefits should be less expensive, because the freedom-of-choice to choose providers is limited to selected physicians and hospitals. Insurance carriers may not add or subtract benefits to the "Medicare

Supplement Insurance'' policies. The only variable allowed is the premium charged.

Medicare + Choice

In 1997, legislation was passed to aid in diminishing the growth of Medicare expenditures and provide more options to participants in the healthcare plans. This legislative modification to a section of the Social Security Act is popularly known as Medicare+C or Medicare+Choice. These arrangements include the offering of managed care plans (health maintenance, provider sponsored, preferred provider, and point of service option), private fee-for-service plans, and medical savings accounts.

THE PRESENT STATUS OF DRUG COVERAGE

Pharmaceuticals are covered for patients who are admitted to hospitals for acute or chronic care. The law does not provide for ambulatory drug coverage. Managed care plans and some supplemental policies may offer a prescription benefit to its senior citizens. Medicare does not directly pay for this coverage. Some Internet pharmacies may attempt to lure unsuspecting patients to their sites with special Medicare prescription plans. It is imperative to recognize that the potential for scams on the elderly exists because of their tendency to be trusting.[7]

The issue of pharmacy benefits becomes more complicated and challenging to implement as each year passes. Medicare will provide coverage for diabetic supplies of glucose monitors, test strips, and lancets. Diabetic drugs are not covered. The present official status is even difficult for providing a simple answer to drug coverage.

> Generally, Original Medicare does not cover prescription drugs. However, Medicare does cover some drugs in certain cases such as immunosuppressive drugs (for transplant patients) and oral anti-cancer drugs.[8]

> There are some Medicare Health Plans that cover prescription drugs. You can also check into getting a Medigap or supplemental insurance policy for prescription drug coverage. Medicaid may also help pay for prescription drugs for people who are eligible.[9]

Many former employers of retired workers provide a level of voluntary prescription benefits in addition to other retiree benefits.

Presently, pharmacists cannot directly bill for providing pharmaceutical services to patients.

Extending Drug Coverage to All Medicare Beneficiaries

Extending the Medicare benefit package to include a pharmaceutical care benefit could close a significant gap in program coverage. The issues revolve around drug costs and services. The various protagonists and antagonists all recognize the cost will be substantial to the taxpayers and participants.[10]

Recently, prescription drug spending has far surpassed growth in spending for other types of healthcare. The rising expenditures have had a significant impact on Medicare beneficiaries, employers who offer retiree health coverage, and on state governments providing drug coverage to the elderly.[11]

The issues involved in providing drug and pharmaceutical care are numerous. They can be examined from the financial and patient care perspectives, and by using management tools.

Medicare participation

Most beneficiaries use drugs. The distribution of the use of drugs is slanted toward patients with chronic conditions of diabetes, hypertension, and cardiovascular diseases. Adverse patient selection to participate is an important issue, because there is an uneven distribution of drug use, and patients must utilize medications over a long period of time.

The financial conundrum. There are a myriad of choices for funding the prescription benefit. Costs could be financed as they are right now with ''Part B'' participation. Beneficiaries and the government contribute to the benefit. Workers and retirees enrolled in employer-sponsored heath plans will have to be taken into account. Beneficiaries who are on Medicaid will present issues that the state and federal governments will have to resolve. Recent drug benefit proposals for the low-income participants have indicated a strong preference for full or partial subsidies for the premium payments and cost sharing for the prescriptions and pharmaceutical services utilized.

Drug benefit coverage

Legislation involving medical and hospital care has always achieved a commitment to comprehensive care. This obligation has not been honored when it comes to providing drugs to patients. Employers and legislators have fashioned creative reasons to provide less than comprehensive care. Since the past is considered prologue, drugs will have to be considered from the vantage point of false economy.

There are various ways to contain the drug benefit. The drug benefit could be restricted by placing a cap on the value of the benefits provided for a benefit period. Another restraint would be to provide drug coverage after a drug benefit deductible was exceeded or only provide the benefit for catastrophic situations. This type of action would save drug money; however, the overall costs for healthcare would probably increase.

The pharmacy profession has recognized that the benefits to society greatly exceed the cost of the drugs. The benefits of the drugs and pharmacy care center around an improved quality of life, a decrease in overall healthcare expenditures, and an increased life span.[12]

Administration of the drug benefit. Proposals being discussed utilize the private-sector model of the Pharmacy Benefit Manager (PBM). Some proposals utilize multiple PBMs for a geographic area, while others rely on a single PBM to manage the program. The issue of whether they will be merely a claims processor or have additional responsibilities is varied. The remaining proposals require government management of the drug benefit. The managerial control would occur at the federal or state level.

Additional tools to manage the pharmacy benefit. Coordination of the Medicare benefit by implementing a multidisciplinary approach to patient care should produce a quality outcome for the beneficiary. From the pharmacy perspective, numerous issues should be addressed.[13] Some of the concerns include:

- *Formulary coverage.* A drug formulary is an instrument that contains safe, effective, and affordable medications designed to improve or maintain patient health. The breadth and depth of coverage and the ability to add drugs are imperative to maintaining a workable drug formulary.
- *Pharmaceutical care and disease management.* The collaborative efforts of the interdisciplinary team of pharmacists and other health professionals help to ensure patients are utilizing medications appropriately.
- *Critical (clinical) pathways and drug step therapy.* These concepts can be effectively used to create a synergistic impact on improving the health of the elderly. Critical pathways are designed to provide continuity of care and decrease the fragmentation of services. Their use helps guide the patient and family through the expected treatments and progress. It also increases the satisfaction of patients, families, health professionals, and the various payers for healthcare services.[14]

Step therapy for the drug treatment of patients creates a "road map" to be used with various medications in order to control the disease or medical condition. The initial step is usually the most common one used in this situation. More complex steps are not attempted to correct the patient's situation until the earlier steps have failed.

Drug evaluation. Drug evaluation is an ongoing, systematic process designed to maintain the appropriate and effective use of medications. It involves the review of the physicians' prescribing relationships, review of the pharmacists' dispensing patterns, and patients' use of medications. This evaluation goes by several names in different healthcare settings.[15] The names include DUR (drug utilization review), DUE (drug use review), and MUE (medical use evaluation).

Resource-Based Relative Value System

Reimbursement for health services is extremely complicated. Providers want higher reimbursement, and payers desire to reduce, maintain, or limit increases paid each year. HCFA developed a methodology to deal with physician reimbursement and allow for an increase in payments for physician services. It is a system based on approximately 7500 relative value service codes. These codes are more complex than the approximate 450 Diagnosis Related Groups (DRG) used by hospitals in their Medicare reimbursement. In addition to the service codes, the formula has a relative value unit (RVU) for practice expenses and a separate one for malpractice insurance. Added to these components is a geographic practice cost index (GPCI) for each defined work service area. The GPCI is designed to take into account high- as well as low-cost practice expenses and physician services as compared to the national average for each constituent of the model. A conversion factor (CF) is also part of the model. This variable is designed to maintain fiscal budget neutrality in the event total payments exceed a certain monetary sum, determined by Congress, each year. The complexities involved can be understood more completely by checking out the designated HCFA web site.[16]

The model used to compute physician payment can be expressed as:

$$\begin{aligned}\text{Physician Payment} = [&((\text{RVU service activity} \times \text{GPCI service activity}) \\ &+ (\text{RVU practice expense} \times \text{GPCI practice expense}) \\ &+ (\text{RVU malpractice expense} \times \text{GPCI malpractice expense})) \times \text{CF}]\end{aligned}$$

The physician payment model is not perfect; however, it represents a quantum leap forward compared to how pharmacy practitioners are reimbursed. The reimbursement in many Medicare+Choice plans, in most state Medicaid programs, and private PBM (third party) arrangements fails to recognize that the costs for providing the pharmacy benefit changes at the practitioner level. PBMs only recognize that the pharmaceutical cost changes.

Conclusion

Medicare represents a federal entitlement program for healthcare services that will continue to expand in coverage of beneficiaries and benefits provided. Providers will be continually challenged to maintain and increase productivity, while payers explore innovative ways to pay for services. A modification of the resource-based relative value scale could be utilized in this endeavor. The drug benefit is exceeding Congressional Budget Office estimates each year. Drug spending for beneficiaries is projected to be $1,500,000,000,000 over the time period 2002–2011. The House of Representatives Budget Resolution allocated $153,000,000,000 for the drug benefit for the same period.[17] The monetary difference is approximately seven times greater than the major political organizations have proposed. The gap between the estimate and the budget amount will require one of several responses. Creative spin masters will have to explain the continued lack of drug coverage, or there will be a final recognition that drugs and pharmaceutical care represent a cost-effective mechanism to aid in controlling healthcare expenditures. "The key to an effective pharmaceutical benefit is management," (and) "a well-trained, well-equipped pharmacist is critically important to the smooth operation of a drug benefit."[18]

MEDICAID

The 50 states, District of Columbia, Puerto Rico, Guam, and the Virgin Islands and other territories all have medical assistance (Medicaid) programs that vary somewhat but are within federal guidelines. States qualify for federal reimbursement by agreeing to provide benefits to certain categories of needy persons who meet the requirements of the block grant for (TANF), temporary assistance to needy families, and the subsequent aid to families with dependent children (AFDC) programs, and for blind and disabled persons receiving social security income.

The program covers children under six years whose family income is no more than 133% of the federal poverty level definition, pregnant women up to 133% of the poverty level, some Medicare beneficiaries, and recipients of adoption assistance and foster care programs. Medicaid covers virtually all outpatient and inpatient health and rehabilitative services, home health, long-term care, dental, prosthetic, pharmacy, and optical services and goods. Pharmacy benefit rules state:

> Prescribed drugs are simple or compound substances or mixtures of substances prescribed for the cure, mitigation or prevention of disease, or for health maintenance, which are prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional practice, as defined and limited by Federal and State law (42 CFR 440.120). The drugs must be dispensed by licensed authorized practitioners on a written prescription that is recorded and maintained in the pharmacists or practitioners records.[19]

While there are over 30 million beneficiaries enrolled in Medicaid, not all of these persons were recipients of services during any given year. Table 1 presents the utilization of various Medicaid services in fiscal year 1998.

Reimbursement

The Health Care Financing Administration (HCFA) establishes the policies that individual State Medicaid programs must adhere to. In the realm of prescription drug reimbursement, rules were established in 1987 for multisource drugs. Upper payment limits based upon estimated

Table 1 Utilizing number of individuals of Medicaid services in FY 1998

Pharmaceuticals	19,337,543
Physicians	18,554,746
Hospital outpatient	12,157,729
Lab/X-ray	9,380,689
EPSDT	6,174,628
Clinic	5,285,415
Dental	4,965,202
Hospital inpatient	4,408,162
Other practitioners	4,341,915
Personal support services	3,108,432
Family planning	2,011,124
Nursing facility	1,645,728
Home healthcare	1,224,714
ICF-mentally retarded	126,490

(From Ref. [20].)

acquisition costs (EAC) were established. For drugs certified by the FDA as being interchangeable, if the prescriber writes on the face of the prescription: "brand necessary" or "medically necessary," the patient can receive the branded product instead of the generic equivalent product. For 1998, HCFA spent $13.52 trillion for 19.3 million recipients which is about $700 per recipient that year.

The top ten states in prescription expenditures for 1998 (in descending order) were California, New York, Florida, Texas, Ohio, Illinois, Pennsylvania, Massachusetts, North Carolina, and New Jersey. The ten lowest expense states were Oklahoma, Arizona. Tennessee, Wyoming, North Dakota, South Dakota, Alaska, Nevada, Hawaii, and District of Columbia. For all states, drugs and related services consumed 9.5% of the total Medicaid budget. Because of this more than $13 trillion expenditure, in 1990, Congress considered alternative means to reduce this expense. The result was a compromise where in exchange for Medicaid formularies to be open to all drugs, manufacturers agreed to agree to a rebate program with HCFA in the OBRA 1990 legislation. Rebates were to be a minimum of 10% of that state's purchases from a company. OBRA was amended in 1992, and today, manufacturers pay 15.1% of the average manufacturer's price back to the state for innovator (single-source) products, and 11% is returned for generic, multi-source products.[21]

To give one a feeling for the quantities involved, the total rebate for 1998 was $2.5 billion. While all drugs should be available, state Medicaid agencies may restrict availability of certain drugs of limited value, regarding safety, effectiveness, or clinical outcome if the drug may be obtained through the prior approval procedure. Other drugs may be excluded completely if they are:

- For anorexia, weight gain, fertility, hair growth, cosmetic effect, smoking cessation, or symptomatic relief of cough or cold.
- Vitamins or minerals or OTC drugs (fluorides and prenatal vitamins excluded).
- Drugs requiring monitoring to be obtained from the manufacturer.
- Barbiturates or benzodiazepines.

A significant component of the Medicaid drug program is a Drug Utilization Review (DUR) activity, which is defined as a structured and continuing program that reviews, analyzes, and interprets patterns of drug usage in a given healthcare environment against predetermined standards. This is conducted for two purposes: to improve the quality of care and to assist in containing costs. OBRA requires that states provide prospective DUR and retrospective DUR programs. The prospective DUR activity is performed at the time of dispensing.[22]

As is the case of an HMO patient presenting a card at the pharmacy, the Medicaid patient does the same thing. Each state decides whether it will have a patient copayment, and if so, its amount. About 15 States have no copayment requirement, and the others charge between 50 cents and $3.00 per prescription.

The pharmacy is paid a dispensing fee that ranges between $3.00 and $5.50 per prescription, depending upon the state. The pharmacy is reimbursed the wholesale price of the drugs minus a discount, which is a percentage reduction from the "sticker" price (called AWP or average wholesale price) which is higher than the actual price paid by most pharmacies due to quantity discounts, direct purchases from manufacturers, and the taking advantage of "deals." The discount averages about 11 or 12% of the average wholesale price. This brings the ingredient reimbursement more in line with the actual price paid by the pharmacy.

For an example, let us consider a drug where the AWP is $60.00. The patient paid $3.00, and the pharmacy will be reimbursed $60.00 less 12%, which equals $52.80 less the $3.00 patient copayment or $49.80 by that state Medicaid agency. In addition, the pharmacy will receive $4.00 as a dispensing fee.

Because of budget problems in some states from time-to-time, limitations have been implemented on occasion. Some states have limited the number of prescriptions per month for limited periods or established caps on the value of the benefits. Usually, these have been lifted when the budget situation improved, especially because there is no evidence that such restrictions are cost-effective overall, and, in fact, there is considerable suspicion that patients might not get needed drugs, resulting in potentially massive hospital or other costs.

With such a huge price tag, HCFA administrators and legislators are always searching for means to reduce costs. Some relief has come from the prior authorization program as well as from a mandatory generic dispensing policy in many states, but additional savings are still desired. There has been discussion about placing recipients in managed care plans that are capitated and having the practitioners control utilization with actual incentives. Some states have asked for supplemental rebates that provide a discount well beyond the OBRA 1990 dictated amount.[23]

Health economists continue to advocate greater emphasis on prevention, screening, patient education, wellness education with emphasis on nutrition, smoking, and alcohol use reduction, avoidance of substance abuse, and

prenatal care as examples of strategies to reduce illness trauma and cost throughout life. Perhaps enrollment in capitated managed care organizations can provide the environment and suitable incentives for greater cost savings in the future.

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PROFESSIONAL DEVELOPMENT

Medical Communications, Clinical Pharmacy Careers in

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INTRODUCTION

Pharmacists rely on medical communications to acquire the information needed to practice pharmacy, but they may not be familiar with the scope of medical communications, much less the potential for an attractive career opportunity in this field. In fact, a popular guide to careers for pharmacists has only one paragraph on the subject.[1] Medical communications refers to the written, audiovisual, or oral dissemination of medical information with a goal of informing audiences about health issues.[2,3] These materials are prepared by medical communicators who are educated in the humanities or sciences, including pharmacy. This monograph describes job activities, work settings, and training and skills for medical communicators. Finally, this monograph explains how pharmacists can become medical communicators.

METHODS

To identify information on careers for pharmacists in medical communications, a database at Virginia Commonwealth University, which includes MEDLINE and 212 other databases, was searched. Because this search did not reveal many useful citations, the director of a biomedical writing program at a university that has an established school of pharmacy (Table 1) was interviewed, as were eight pharmacists who had at least 10 years of experience in medical communications and who represented different work settings; the mean duration of experience was 15 years (range: 10–21 years). Approximately 30 questions were developed, consent was obtained to record and quote the interviewees, telephone interviews were conducted in June 2000, and interviewees were invited to review the first draft. The information in this chapter is based on these interviews, unless otherwise stated.

Two additional interviews were conducted to obtain missing data. To supplement salary information, we contacted Beth Rhoads of Pharmaceutical Search Professionals, Inc. (North Wales, PA). To determine where pharmacists find employment as medical communicators, membership data were collected from the American Medical Writers Association (AMWA).

WHAT DO MEDICAL COMMUNICATORS DO?

Medical communicators prepare many types of projects for health care professionals, consumers, regulatory agencies, and other audiences. To convey information to different target audiences, medical communicators use traditional media, such as books, journals, slides, and other newer media, such as compact discs and the Internet (Table 2). Most of these projects begin as written manuscripts, but medical communicators perform other types of activities, such as editing, interviewing, and moderating focus and other discussion groups.

Writing or editing a manuscript for publication in medical journals is a popular type of project. A medical communicator can collaborate with clinical investigators to transform a clinical trial report into an original research article. Hamilton said, "Medical writing is perceived as a difficult task, so investigators are happy to delegate the work." The medical communicator can identify references to be cited in the introduction and discussion, develop an outline, write the first draft, incorporate author's changes, and style the manuscript for submission to the target journal.

Additional examples of popular projects are preparing monographs and regulatory documents. A monograph describes a topic, such as a drug or disease, for the purpose of

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Table 1 Medical communicators interviewed in June 2000[a]

Interviewee	Title and affiliation
Freelance setting	
Donna K. Curtis, PharmD	Freelance writer, Curtis Consulting & Communications
Cindy W. Hamilton, PharmD	Freelance writer, Hamilton House® Medical and Scientific Communications
John Russo, Jr., PharmD	Freelance writer, Medical Communications Resources
Medical communications or pharmaceutical company	
Karen M. Overstreet, EdD, MS, RPh	President, Meniscus Educational Institute, a division of Meniscus Limited
Gary E. Pakes, PharmD	Senior Medical Publications Scientist II, Glaxo Wellcome, Inc.
Nancy C. Phillips, BS, RPh	President, The Phillips Group
Publisher, professional association, or both	
Eugene M. Sorkin, PharmD	Associate Editor, *The Annals of Pharmacotherpy*, Harvey Whitney Books
Cheryl A. Thompson, MA, RPh	Editor, American Society of Health-System Pharmacists
University	
Lili F. Vélez, PhD	Director, Biomedical Writing Program, University of the Sciences in Philadelphia
Other	
Beth Rhoads, BS	Recruiter, Pharmaceutical Search Professionals, Inc.

[a]Some titles and affiliations have changed since the interviews were conducted.

providing continuing education or promoting a new drug. Regulatory documents are required for drug development; examples include clinical investigator brochures, clinical trial reports, new drug applications, and package inserts. With these projects, the medical communicator can research the literature, collaborate with other team members to analyze and interpret data, write an outline and then the first draft, edit it, and coordinate revisions. In the case of a monograph, the medical communicator can work with a graphic artist to design and produce a printed product.

Table 2 Scope of medical communications

Types of projects		
Abstracts	Grant applications	Policy writing for professional practice
Bibliographies	Journal articles	Practice guidelines
Book reviews	Marketing and promotional material	Product monographs
Case histories and reports	Medical letters	Proposals for new business
Clinical investigator brochures	New drug applications	Sales training
Clinical trial reports	Package inserts	Study protocols
Continuing education (CE) programs	Patient education material	
Activities		
Critically evaluating the literature	Moderating focus groups	Writing
Editing	Researching	
Interviewing	Reporting	
Media		
Audio	Journals	Radio
Books and book chapters	Monographs	Slides
Compact discs	Newsletters	Television
Internet	Newspaper articles	Video

(From interviews and Ref. [2].)

Table 3 Estimated annual income for pharmacists employed as medical communicators in different settings in June 2000

Employment setting	Annual income ($)	
	Starting	Maximum
Contract research organization	45,000–65,000	85,000–90,000
Freelance setting	50,000–80,000[a]	90,000–200,000+
Medical communications company	55,000–70,000	100,000–130,000
Pharmaceutical company	55,000–70,000	100,000+
Publishing company	45,000–50,000	100,000
Professional association	Not available	Not available
University	Not available	Not available

[a]Based on hourly rate × 1000 billable hours/year.
(From interviews and Ref. [3].)

WHERE DO MEDICAL COMMUNICATORS WORK?

Medical communicators work in many settings, such as pharmaceutical companies, medical communication companies, freelance situations, professional associations, publishing companies, and universities. Pharmacists can also work in these settings (Table 3), but the salaries are not always competitive with those in traditional pharmacy practice sites. One way to estimate where pharmacists work as medical communicators is to compare the primary sections chosen by pharmacists who join AMWA with those chosen by the entire membership. The primary sections are pharmaceutical; freelance; editing/writing; public relations, advertising, and marketing (PRAM); and education. AMWA membership data confirm that pharmacists ($n = 137$) choose the same primary sections as the entire membership ($n = 4637$), but there are some differences in distribution (Fig. 1). For example, pharmacists were most likely to choose the pharmaceutical section, whereas the entire membership was most likely to choose the editing/writing section. Unfortunately, our survey was not designed to determine the reasons for these differences, and only limited salary information was available for each setting. Additional limitations of our survey were small sample size and potential for overlap between sections. Finally, our survey did not capture membership data for pharmacists who do not have the PharmD degree because this was the only relevant searchable term.

Interviewees described advantages and disadvantages associated with their positions, some of which recurred in different work settings. For example, Pakes enjoys his position in international medical publications at a

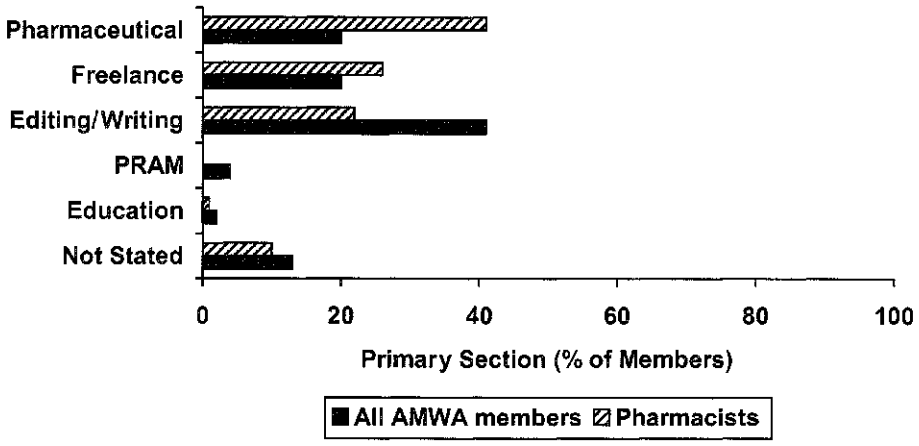

Fig. 1 Primary section in American Medical Writers Association (AMWA) chosen by all members ($n = 4637$) and pharmacists ($n = 137$) in July 2000. PRAM = public relations, advertising, and marketing.

pharmaceutical company because it is intellectually challenging and, with the finished product, "there is something tangible." Pharmaceutical companies offer opportunities for advancement and comprehensive benefits such as a retirement package; paid vacation, holidays, and sick leave; and medical and dental insurance. Entry-level salaries can be higher than in some settings because pharmaceutical companies typically require some experience.

Medical communication companies prepare educational, promotional, and regulatory materials, usually for pharmaceutical companies. Contract research organizations, which oversee clinical trials for pharmaceutical companies, may also prepare regulatory materials. Phillips said that her job at a medical communications company "allows me to work with some of the leading physicians and pharmacists in the world." Overstreet added that her position allows her "the flexibility to do a variety of different things every day, and the opportunity to learn about new techniques and new therapies to supplement my pharmacy background." Benefits vary depending on the size of the organization. There are opportunities for advancement to positions such as editorial director or even president, but Phillips lamented that she has less time to write now that she is president of her own company.

Freelance was the second most popular AMWA section chosen by pharmacists. Advantages include working in a home office and being self-employed, independent, and flexible. Russo explained, "As a freelancer, I'm able to choose the projects that I'm interested in doing." Curtis, Hamilton, and Russo agreed that freelance writing has some disadvantages, especially regulating the workflow. Curtis explained, "Often you are juggling projects with very tight deadlines for multiple clients, and every client is important, so things can get really stressful." The earnings potential for freelancers appears to be one of the highest in medical communications, but this can be misleading because self-employed people must pay for their own equipment, benefits, and the part of social security that is otherwise paid by employers. In addition, freelancing can be very solitary because of minimal interaction with professional colleagues and patients.

Pharmacists who work at professional associations and publishing companies solicit manuscripts for journals, organize the peer review process, and edit manuscripts. Pharmacists also write news, editorials, and monographs for their journals, newsletters, web sites, and other publications. Thompson likes being an editor at a professional organization because her job encourages creativity, but she admitted that "being an editor is not a 40-hour a week job and sometimes I feel overwhelmed." Salary information is not available for pharmacists who work in these settings, but Thompson said, "Medical communicators should expect lower wages from non-profit organizations like ASHP." The benefits, however, are comparable to those offered by pharmaceutical companies, and there are opportunities for advancement. Sorkin said, "There is a trade-off and people just have to determine what works best for them."

WHAT TRAINING AND SKILLS ARE NEEDED?

The minimum training and skill requirements for a medical communicator are knowledge of medicine and ability to communicate. Hamilton explained, "By their training, pharmacists know and understand medicine and the drug development process." Curtis added, "Having the clinical knowledge about drugs and therapeutic areas really helps to bring some expertise to the writing." Another relevant aspect of pharmacy training is drug literature evaluation, because medical communicators

Table 4 Resources for pharmacists interested in learning about career options in medical communications

Type of resource	Example[a] (Internet address)	Comments on example
Professional organization	American Medical Writers Association (www.amwa.org)	Annual conference, regional meetings, workshops, networking
Colleges and universities	University of the Sciences in Philadelphia (www.usip.edu/graduate/biomedical_writing.htm)	Degree in biomedical writing, article on career opportunities (www.home.earthlink.net/~rhetrx/bmw/)
Practical experience	Hamilton House (www.hamiltonhouseva.com)	Clerkship for pharmacy students, list of recommended books

[a]The examples were selected because they provide information available on the Internet, including links to other useful web sites.

are expected to research new therapeutic categories. It is also helpful to have good computer skills, including familiarity with word processing and presentation software.

All but two of the interviewees agreed that good writers are trained, not born. Vélez said, "A writer is simply someone who is willing to keep at it." Pakes disagreed and said, "I don't think that you can take just any old pharmacist and turn them into a writer. A person is either a writer or they're not. What you do is you hone your skills and become a better writer."

Regardless of whether good writers are trained or born, good medical communicators must be organized, accurate, flexible, curious, self-motivated, disciplined, and able to meet deadlines. Good pharmacists also have many of these qualities. Hamilton explained, "Pharmacists are typically very well organized because we are trained to put the right medication into the right bottle and administer it at the right time. These skills are transferable to medical writing."

Another skill that is transferable from some pharmacy settings to medical communications is the ability to manage a business. This is especially important for the individual freelance writer who must balance the time required to manage the business with the time required to write and generate income. Russo said, "You need to have an appreciation and an understanding of marketing" to thrive in the freelance business.

HOW CAN PHARMACISTS BECOME MEDICAL COMMUNICATORS?

There are many ways for pharmacists to obtain training and improve their communication skills (Table 4). Professional organizations offer workshops on writing and other relevant topics. For example, AMWA, an educational organization that promotes advances in biomedical writing, offers a certificate for completing their core and advanced curricula.[4] Workshops are available at the popular annual meeting in late autumn, at regional meetings throughout the year, and through an onsite option. AMWA membership also provides credibility and a venue for networking, which can lead to writing assignments or even full-time employment.

Colleges and universities offer courses and degrees in technical writing, journalism, and communications. The University of the Sciences in Philadelphia offers a master's degree in biomedical writing, the only degree program of its kind in the United States. According to Vélez, about one-fourth of the students in the master's program are pharmacists, and many other pharmacists take classes as nonmatriculating students or via the Internet.

A degree in biomedical writing is not likely to become a prerequisite for a career in medical communications, according to the interviewees. Vélez explained, "There is a lot of lost creativity and innovation when you force people to have a particular credential before they can participate in a certain field." However, Vélez continued,

> Traditional pharmacy education does not stress written communication abilities. This means pharmacists interested in biomedical writing could probably benefit from additional coursework. Knowing *why* a text needs to be written in a particular way gives you more confidence and flexibility than only knowing *what* needs to be written.

Practical experience is also available. Pharmaceutical companies, professional associations, and publishers offer residencies and fellowships in medical communications or related areas, such as drug information. Schools of pharmacy offer clerkships for students under the direction of medical communicators. Finally, there is on-the-job training. Overstreet said, "PharmDs are a hot commodity right now, even without experience. Some employers are willing to accept a new PharmD graduate and train them themselves."

Interviewees offered advice for making the transition from traditional pharmacy practice to medical communications. To learn how to differentiate between good and bad writing, pharmacists should read and critically evaluate the published literature. To gain insight about career opportunities, pharmacists can interview a medical communicator[5] or search the Internet; some web sites[3,6] offer links to other useful sites. To develop a writing portfolio, pharmacists should write for publication; an example of a popular target for new writers is a newsletter published by an institution or local professional association. In fact, pharmacists can try medical writing on a part-time basis while maintaining a traditional pharmacy career.[2] Sorkin concluded, "If you're interested in medical writing, you just have to get into it and do it. You won't know how good you are and if you like it until you do it."

CONCLUSIONS

Medical communications is an attractive career option for pharmacists because jobs are available and pharmacists are well suited for the work. Employment is attainable in many settings, some of which offer competitive salaries. Sorkin attributed the abundance of career opportunities to

the growing demand for medical information because medical communicators are the conduits for that information. For example, the Internet is creating a surge in the demand for direct-to-consumer access to complex medical issues. Thompson predicted, "There is going to be a greater need for people who can explain medical information to consumers."

Finally, pharmacists who work as medical communicators generally like their jobs often because the work is intellectually challenging, and medical communications is a natural extension and application of the education and skills characteristic of pharmacists.[2] They have a great advantage compared with many other professionals who want to redirect their careers. As Vélez explained, "Pharmacists don't have to walk away from their years of specialized education. Pharmacists can bring that expertise right into their new lives as writers, and employers will love them for it!"

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Medical Information, Industry-Based

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INTRODUCTION

Medical information departments in the pharmaceutical industry vary greatly from one company to another in size, scope, level of responsibility, and even placement in the company. Typically, these departments can be located under the umbrella of research and development, sales and marketing, or medical affairs. In a survey conducted by Ernst and Young,[1] 75% of the industry' s medical affairs and drug information departments report to clinical (or medical) groups versus sales and marketing. The group may also have several different names such as medical information, professional services, scientific information, or medical communications. For the purposes of this discussion, the designation medical information department is used. It is important to note that the group exists to support the company in its efforts to provide quality pharmaceutical products in respective therapeutic areas.

DISSEMINATION OF DRUG PRODUCT INFORMATION

Guidelines and Limitations

The primary responsibility of any medical information department is the provision of product-specific information to healthcare professionals and/or consumers in response to specific inquiries. If a response to a question involves information outside the Food and Drug Administration (FDA)-approved package insert/labeling, the information is considered to be "off label," and several factors limit the way in which information is communicated to the customer.

The FDA guidance that addresses the dissemination, by pharmaceutical manufacturers, of information on drugs and devices exists in response to the issue of off-label information. This type of information can be provided to a caller from the medical information department; however, it does not serve as a recommendation from the company. The FDA views the support of a medical information department as the exchange of scientific information among healthcare professionals and allows that information to be exchanged only in response to a spontaneous request from a caller. In other words, by providing information that the caller has not requested, promotion is assumed. The FDA Modernization Act of 1997 states that a manufacturer can disseminate information in response to an unsolicited request from a healthcare practitioner.[2] A disclaimer that establishes that the data provided are to be used by the caller only for their scientific information is always stated either verbally or in writing, depending on which is applicable to the given situation. In contrast, sales representatives are not at liberty to discuss off-label topics.

The information disseminated must be scientifically balanced; however, it must also be "fair balanced." This refers to the inclusion of negative as well as positive information. If the indications of a drug are being described, so too must the contraindications be described; if the efficacy is described, so too must the safety of the product.

In general, a medical information staff member can answer an off-label question if the request is of a spontaneous and unsolicited nature, if the response contains both scientific and fair balance, and if an appropriate disclaimer is included. Each company must interpret the FDA guidances and develop policies with respect to the details of how information is disseminated to healthcare professionals. The FDA does not provide any guidelines that delineate how to address consumer inquiries. Each company must again develop policies regarding the dissemination of information to consumers. The majority of companies in the United States limit discussions with consumers, if any occur, to data contained in the product's package insert (PI) or the patient package insert, if available.

Drug Information Resources

Package labeling

In the realm of the pharmaceutical industry, the FDA-approved package insert/labeling is the document used

to answer questions with regards to company recommendations. The PI, as it is known in the United States, is a summary of the new drug application (NDA) provided to the FDA from the manufacturer for the approval of a new product. This summary reflects in-depth discussions between the FDA and the manufacturer, and generally represents certain compromises on the part of both parties. The information within the PI becomes the foundation for approved promotional materials and is used by healthcare professionals as general guidelines for the use of the product, although the entire wealth of information known about any given product is not included in the PI. The PI should be the first resource used to answer an inquiry. Even if additional off-label information on a specific topic is provided, the PI data/recommendations should be described first.

Primary, secondary, and tertiary references

As in university or academic-based drug information centers, published literature used to develop an answer to a drug information inquiry can be divided into primary, secondary, and tertiary sources. Primary sources are the most desirable type of data to use and can be subdivided, depending on the type of data collected. Information gleaned from randomized, prospective, double-blind trials result in data more useful than just one case report on a given topic. Ideally, the most rigorous data available are used; however, case reports and abstracts may be the only available literature published. Peer-reviewed, well-respected journals should be used.

Secondary resources such as pharmacopeias and reference texts can be used for very basic information, but the health professional customer usually has these types of resources available. Data described in a review article should be traced to their original reference if said data are to be used to answer a query.

Tertiary references, such as textbooks, may be used for background information necessary to research a given topic such as a rare disease state.

Data on file

Manufacturers retain considerable data on file that are not found in the public literature. These data can include such information as extended stability studies, compatibility studies, drug safety reports, and comprehensive information in the NDA. The guidelines regarding dissemination of this data are subject to company policies and are typically used when no published literature is available. If the data are used and referenced in any communications with healthcare professionals, the data must be easily retrieved, if required.

Summary

In summary, the development of a well-balanced reply to an inquiry involves the use of published materials in the same manner as that conducted in an academic or clinical setting. In an industry setting, PI information and unpublished data on file with the company are used. In addition, the information communicated must be scientifically accurate, balanced, supported by appropriate literature, and should not include the author's editorial perspectives.

MANAGING THE DAILY WORK FLOW

Customer Base

Medical information staff receive questions from a varied source of customers, including healthcare professionals practicing in clinical/academic settings employed by managed care organizations, pharmacy buying groups, and health maintenance organizations; and consumers. These callers are considered external customers. The mix of these calls will depend on the type of products manufactured by the company. A company whose products are all prescription intravenous drugs will have more calls from health professionals, whereas a company where the majority of products are oral, over-the-counter (OTC) medications will receive more calls from the consumer market. In addition, the type of health professional calling depends on the types of products produced.

The services of the medical information group are also used by "internal customers," that is, other departments within the pharmaceutical company. The group supports internal customers in the same fashion as external ones. The communication with the field sales force is extremely important. It is imperative to impress upon sales representatives the limits of their ability to answer questions. Questions that include information outside the package insert should be referred to the medical information group.

Volume and Type of Requests

The numbers of questions received varies greatly based on several factors. Although companies with more products usually receive more calls, they may also have more mature drugs in their catalog. Drugs that are further along

in the life cycle may generate less interest in the medical community and therefore fewer calls. Along similar lines, the type of inquiry depends on the type of product. Intravenous products used in an acute setting may generate questions of a clinical nature that require more in-depth research than that of a consumer call regarding an OTC product and its proper storage.

Triage Procedures

The efficiency with which requests are handled reflects on the level of service that a medical information department provides. The organization of the medical information group depends on the size of the company and the department, as well as the number of products the department supports. The phone triage may begin with an administrative representative who can refer the call to the appropriate healthcare professional. In larger groups, there may be a two-tiered system whereby a trained nonhealth care professional service representative may answer standard questions with scripted answers. If a question cannot be appropriately answered with the information available to them, the call is referred to the next tier of health care professionals, typically pharmacists, nurses, or physicians. Calls may also be received via the Internet through a company's web site, by fax, or by mail. Procedures for the efficient routing of these inquiries must also be in place.

Third-party companies who specialize in the provision of medical information may also be used. This outsourcing of responsibilities may be done in anticipation of a large increase in call volume (e.g., the launch of a new product) or may be used by companies who choose not to maintain a call center as part of the organization. In both cases, there are usually medical information staff employed by the pharmaceutical companies who develop and maintain a library of standard information (or scripts) used by the first tier of company representatives or by third-party organizations to answer queries. After-hours coverage may be provided through a pager or an answering service.

Documentation

Regardless of the type of product, every call must be documented. Documentation serves several purposes, including to store data for report generation; to create a database that can be repeatedly used to answer questions; and to meet legal needs in case of litigation. Most industry-based medical information departments maintain a library of "standard answers" that consist of replies to frequently asked questions. Commercially available electronic databases are available specifically for this setting. These types of databases enable the medical information representative to document all calls; store, generate, and maintain standard replies; and generate reports as needed. Systems of this nature can be customized to a degree for the particular needs of the company. Alternatively, similar systems can be developed by a company's own information systems department.

INTERNAL SUPPORT FUNCTIONS

Services provided by any given medical information group vary greatly. In general, however, the group is a service provider for the company at large and those services can be employed by all departments including, but not limited to, the sales and marketing, regulatory affairs, and clinical research departments.

Sales

The medical information group can support the sales group in many ways. Invariably, the sales organization is the most frequent user of the medical information department, with respect to internal customers. The sales organization relies on the medical information department to answer or clarify any questions they have regarding the products they sell and related issues. They also refer questions from their customers to the medical information department who in turn communicates with the customers. Additional support may include product training and educational newsletters to equip the sales force with new information that has been published regarding the products they sell or competitors' products. More often than not, this information is off label and serves to educate the sales force and prevent them from hearing news (positive or negative) about their products from their customers. Although they cannot discuss this information with the customer, they will still be aware that the medical information group has developed a reply to queries regarding new published data.

Marketing

The marketing department works not only on the "dollars and cents" of selling products, but also on how to best position products in the marketplace. In the development of advertising campaigns and key messages, the medical information department can be very helpful in ensuring

the accuracy of the data and the fair balance with which the data are used.

Regulatory Affairs

Safety reporting

All pharmaceutical manufactures have a group devoted to safety issues and the reporting of adverse events to the FDA according to specific regulations. However, the report of an adverse event (AE) may initiate within the medical information group. A caller may contact the company to inquire about the incidence of a specific AE or to ascertain how to treat a specific event. The caller may have no intention of reporting an AE; however, it may become clear from the conversation that an event has actually occurred. If four specific pieces of information exist—an identifiable patient, identifiable reporter, an identifiable drug, and an identifiable event—the company is obligated to report the AE. Because many of the regulations are time sensitive, medical information groups must work hand in hand with safety groups to assure that AE reporting is done in a timely fashion. Some pharmaceutical companies combine the medical information and safety departments, typically in the setting of a small company.

Quality assurance

As part of the regulatory affairs department, the quality assurance groups often call upon the medical information department to assist in ensuring that data used in any formal documentation that they review (from NDA submissions to changes in the package insert to new advertising campaigns) are accurate and appropriately used.

Clinical Research

Clinical research teams work on investigational trials from the time a product reaches phase II clinical development through FDA approval. Medical information staff use their expertise to assist in protocol development, medical writing, and researching drug or disease state questions that may arise in the course of these trials.

COMMITTEE INVOLVEMENT

As in any organization, pharmaceutical manufacturers develop committees to make decisions, initiate new programs, and maintain specific procedures. Many of these committees include representation from many different groups in the organization, each contributing their expertise in a given area. The following is meant to exemplify several types of committees that may have medical information representation, but is not meant to be all inclusive.

Labeling and Promotional Review Committee

All the information included in a product's package labeling is under careful scrutiny by the FDA. The development of the insert is usually done with the input of clinical research, sales and marketing, medical information, regulatory affairs, legal, pharmaceutical sciences, and other appropriate groups, depending on the nature of the product. All these departments are represented on this type of committee. The drafts of the initial PI are reviewed, edited, and agreed upon by the members of the Labeling and Promotional Review Committee prior to submission to the FDA. Even after final development and FDA approval of the initial PI, any change in the labeling (from storage changes to new indications) must be reviewed by the Labeling and Promotional Review Committee. All advertisements and promotional materials must be reviewed by this committee. A representative from the medical information group well versed in the literature for a given product serves as a valuable contributor to this committee, lending an objective view of the information presented.

Publications Committee

When research projects sponsored by pharmaceutical companies are complete, investigators often write reports of the results and submit them for presentation and/or publication. The writing of these reports is often completed with the assistance of professionals from the medical information department and other involved departments in conjunction with the investigators. In addition, most companies have a publications committee to map out where and when reports should be submitted.

Global Medical Information

The pharmaceutical industry has become a global business. Companies have headquarters in a specific part of the globe, with subsidiaries in many other locations. It becomes important to communicate with medical information colleagues in those subsidiaries to ensure that consistent messages are being communicated globally regarding the same products. Information must always be

tailored for the specific location because government-approved indications and labeling for the same products may vary by country.

EDUCATION

Because a medical information group is considered to be a support service for the company and its customers, a logical extension is to provide education for those customers.

Continuing Education (CE)

Decreasing budgets and staffing have made it increasingly difficult for health professionals to regularly attend large off-site meetings. Therefore, the provision of high-quality CE at local presentations or as home study programs is a well-received service that a medical information department can initiate and develop. Guidelines set by the FDA and the individual accreditation organizations for each type of professional CE vary greatly. Accreditation must be received by each institution separately and care must be taken to abide by all respective guidelines. In general, educational pieces are given as live presentations or self-study programs authored by outside experts that should not be influenced by the company.

Employee Education

As described previously, the medical information department can provide learning tools to enable the sales organization to remain current on their product line. These communications can be made available to all employees to educate them on the products they support.

Academic Rotation Site

As opportunities for pharmacists in nontraditional roles continue to grow, the medical information department of a pharmaceutical company provides a unique student clerkship site. Pharmacy students experience a different medical information practice while learning the organizational makeup of a corporation versus an academic, hospital, or retail setting. In addition, students can be exposed to many opportunities afforded to pharmacists in departments outside the medical information departments.

CONCLUSION

The primary objective of an industry-based medical information department is to provide accurate, well-balanced, and timely responses to inquiries regarding a company's products. However, the department can be involved in every aspect of the life cycle of a pharmaceutical product. The level of that involvement depends on the size and organization of the company, as well as the initiative and creativity of the medical information staff.

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Medicare Benefits and Improvement Act of 2000 for Outpatient Immunosuppressive Agents

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INTRODUCTION

Immunosuppressive therapy is life long, or is needed for as long as the individual has a functional transplanted organ, and the cost of therapy often exceeds $10,000 annually. Since the mid-1970s, the question of how to help patients pay for immunosuppressive therapy has received congressional attention. The Medicare Benefits Improvement and Protection Act of 2000 (BIPA 2000) addresses Medicare time limitation for outpatient immunosuppressive coverage.

COVERAGE UNDER MEDICARE

Outpatient immunosuppressive medications—most commonly, azathioprine, cyclosporine, mycophenolate, prednisone, sirolimus, and tacrolimus—are covered by Medicare Part B. Currently, medicare pays for 80% of immunosuppressive drug therapy. The other 20% is the patient's responsibility. To qualify for Medicare immunosuppressive coverage, the patient must have the following:

1. Medicare benefits due to *age*, *disability*, *or end-stage renal disease (ESRD)*.
2. Medicare part B.
3. Received a solid organ transplant that was medicare "covered" at the time of transplant.
4. Surgery performed at a medicare-approved transplant facility.
5. A viable transplanted organ.

Prior to January 2000, medicare provided outpatient immunosuppressive therapy for 36 months posttransplant to patients who were Medicare eligible due to age or disability and met criteria in items 2–5 listed previously. As of January 2000, eligible beneficiaries whose Medicare coverage for immunosuppressants expired during the year 2000 received an additional 8 months of Medicare coverage beyond the 36-month period. In December 2000, President Bill Clinton signed the Medicare BIPA 2000, which eliminated the time limitation for Medicare benefits for immunosuppressive drugs for patients who receive Medicare benefits due to age or disability. A program memorandum from the Health Care Financing Administration stated:

> Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no longer any time limit for Medicare benefits. This PM supersedes PM AB-99-98, which describes the method for determining the former time limit for this benefit that applied to drugs furnished prior to December 21, 2000. This policy applies to all Medicare entitled beneficiaries who meet all of the other program requirements for coverage under this benefit. Therefore, for example, currently entitled beneficiaries who had been receiving benefits for immunosuppressive drugs in the past, but who immunosuppressive drug benefit was terminated solely because of the time limit described in PM AB-99-98, would now resume receiving that benefit for immunosuppressive drugs furnished on or after December 21, 2000.[1]

Therefore, BIPA 2000 expanded Medicare benefits to lifetime coverage, or for as long as the patient needs immunosuppressive therapy, for patients who have Medicare due to age or disability. The lifetime coverage benefits of BIPA 2000 do not include patients who have Medicare based solely on ESRD. Currently, those patients who have Medicare due to ESRD only and meet criteria in items 2–4 will receive immunosuppressive coverage for 36 months posttransplant.

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Medication Assistance Programs, Pharmaceutical Company-Sponsored

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INTRODUCTION

Pharmaceutical company-sponsored medication assistance programs are a philanthropic effort promoted by the pharmaceutical companies to provide medications free or at reduced prices to eligible patients who cannot afford prescription medications or have no other means of obtaining them.[1–3] Although more than 2.7 million prescriptions costing over $500 million were filled through medication assistance programs in 1999, every prescription medication cannot be obtained through medication assistance programs. The existence of an assistance program is determined by the manufacturer of the medication.[3]

MEDICATION ASSISTANCE PROGRAMS

Pharmaceutical companies offer many different types of medication assistance programs to help qualifying patients obtain prescription medications. One type of assistance program includes providing free or reduced prices for medications to patients who financially qualify. For eligible patients, the medication may be received by mail, from a local pharmacy, or from the prescribing physician. Another type of assistance program involves helping to determine the patient's healthcare coverage, identifying billing claims for medications, and attempting to resolve denied medication claims. Some manufacturers offer payment limitation programs, where the companies set an annual drug cost limit, and when costs exceed the limit, they are absorbed by the manufacturer. For all of these programs, eligibility criteria are established by each company's assistance program and may require that the patient have no prescription coverage or limited prescription coverage, that the patient has reached a certain medication cost, and/or has limited income and assets to afford the medication.

The references cited in this text provide a listing of some medications that can be obtained through medication assistance programs. For the most current information concerning pharmaceutical company-sponsored medication assistance programs, contact the manufacturer of the medication. Additional sources of information include Web sites (Table 1), publications including the *Reimbursement Assistance Programs Sponsored by the Pharmaceutical Industry* and the *Directory of Prescription Drug Patient Assistance Programs* published by the Pharmaceutical Research and Manufacturers of America, and healthcare professionals such as social workers and pharmacists.[3]

Enrollment

Patient enrollment in these programs is usually initiated by the patient's physician, although enrollment may occur by the patient, a patient advocate, or other healthcare professionals. Information frequently needed to process the application is listed in Table 2. Regardless of who initiates enrollment, the prescribing physician has to participate in the process.

Companies have their own processes for patient enrollment that typically require the completion of an application and a reporting of the patient's health insurance coverage, assets, income, and liabilities. A prescription for the medication is usually required. Many programs allow enrollment over the phone, while others require written correspondence. In order to determine eligibility, many companies require verification of a patient's financial status by documents such as income tax returns, W-2 forms, social security and other benefit

Table 1 Internet sites providing information concerning medication assistance programs

www.themedicineprogram.com
www.needymeds.com
www.phrma.org/patients
www.familyvillage.wisc.edu

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Table 2 Information frequently requested by medication assistance programs

- Patient and physician's names and contact information
- Physician's state license number and drug enforcement number
- Name, strength, and amount of medication requested (prescription)
- Patient's income and other financial disclosures
- Patient's insurance coverage
- Patient and physician signatures

reports, and asset statements. Once the information is received by the company, it is then evaluated and the patient's acceptability is determined.

Medication

Once enrolled in the program, the medication may be provided free, or patients may be required to pay a co-payment or shipment charge. Medications are supplied by direct delivery to the patient or physician, or the patient may be issued a benefit card or voucher to be presented at a pharmacy. The amount of medication supplied and the enrollment period varies according to the program.

Pharmacists' Role

Pharmacists can play an important role in this process. Pharmacists can inform patients and other healthcare professionals about the availability of pharmaceutical company medication assistance programs, initiate the enrollment process, and develop strategies that use medication assistance programs to reduce institutional financial losses.[4,5]

ETHICAL ISSUES

Two ethical issues concerning pharmaceutical company-sponsored medication assistance programs include drug diversion and the reporting of false information to obtain medications. Drug diversion and the reporting of false information may lead pharmaceutical manufacturers to consider ending the assistance program or creating more stringent eligibility criteria. Therefore, it is important to ensure that patients report accurate information during the enrollment process and that the intended party receives the medication. By adequately screening and monitoring information, healthcare professionals will be able to ensure that patients in need receive the intended benefits of these programs.

CONCLUSION

Many patients cannot afford to purchase needed prescription medication. Approximately 16% of the U.S. population does not have any health insurance, and a greater percentage has health insurance without prescription medication benefits.[6] Pharmaceutical company-sponsored medication assistance programs provide valuable options to both patients and healthcare providers by providing drugs to patients who have limited means of purchasing their medications.

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Medication Errors and Adverse Drug Events Prevention

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INTRODUCTION

Around 1995, the U.S. public began to become much more aware of the risks associated with medications as there was a series of highly publicized medication errors and adverse drug events (ADEs), such as the fatal Betsey Lehman chemotherapy overdose.[1] In November 1999, the Institute of Medicine (IOM) Report concluded that medication errors and ADEs were in the top 10 causes of American deaths. The report detailed many strategies to reduce medication errors and ADEs, and called upon healthcare organizations and professionals to give a higher priority to safe medication systems.[2] In interviews with hospital patients, a survey found the most common fear of patients was being give two or more medications that interacted to produce a negative outcome.[3]

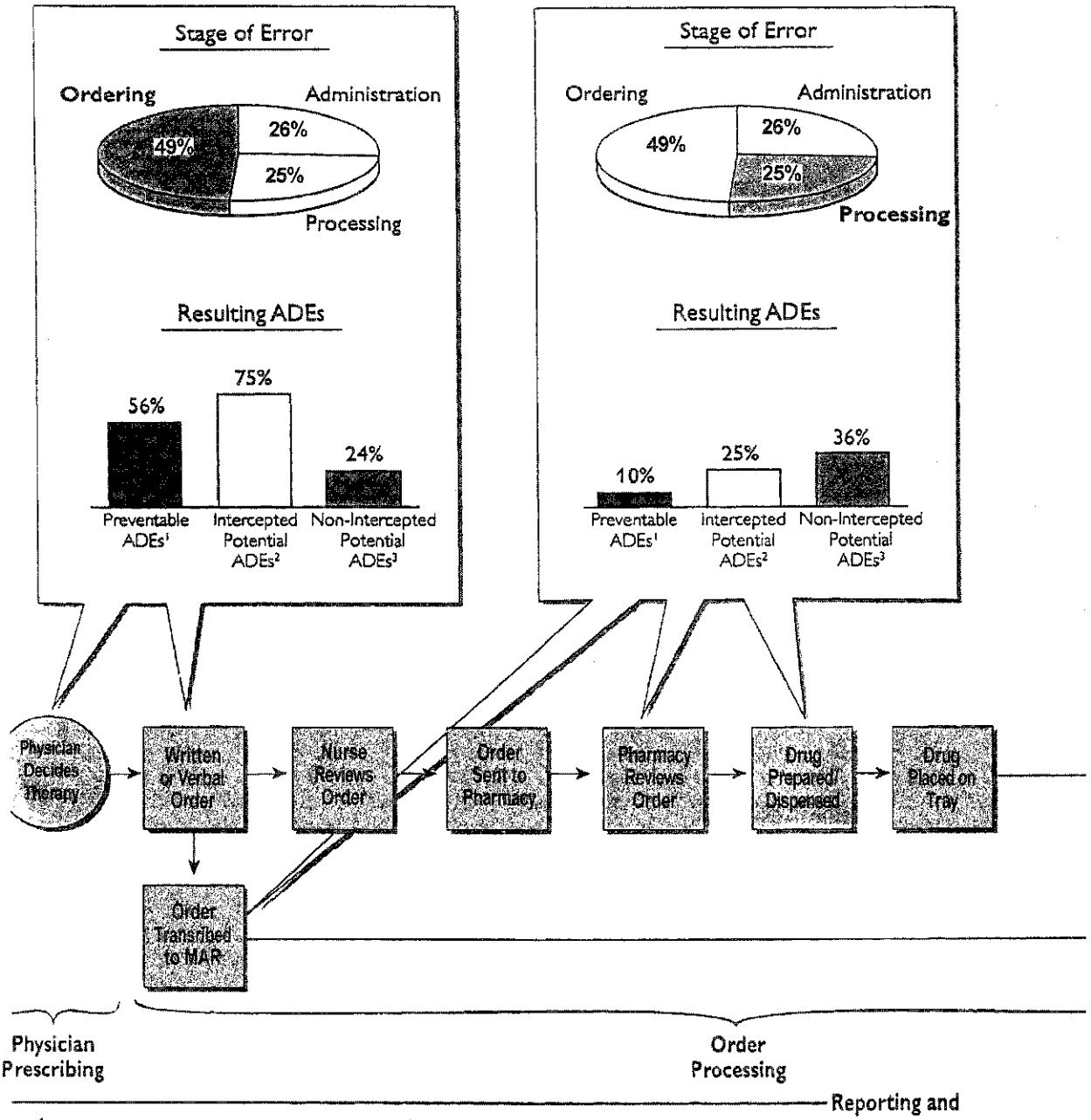
Health care providers and organizations have accelerated the search for ways to make the medication-use process safer for patients. Numerous prevention strategies have been developed.[2,4–6] Although well intended, some of the strategies have introduced different complexities and workload into a medication-use process that had all ready demonstrated its fragility. More effective methods for decreasing medication errors and associated ADEs have to be designed, implemented, and evaluated post-implementation. This article describes how changes in the medication-use cycle can significantly reduce medication errors and preventable ADEs. It is not intended to replace comprehensive references already available,[2,4–6] but to introduce key ideas into the body of knowledge about medication error and ADE prevention.

THE MEDICATION-USE CYCLE

A medication error happens when there is general agreement that a person should have done other than what they did and so the person is labeled as having committed a medication error.[7] An ADE occurs when patient harm occurs as a result of a medication error (e.g., wrong medication given) or a patient idiosyncrasy (e.g., a previously unidentified allergy to penicillin). Preventable ADEs usually result from medication errors, but not all medication errors produce ADEs.

Fig. 1 lists the typical steps and personnel involved in the medication-use cycle in the acute care setting. In the ambulatory setting, the patient or family instead of the nurse would be receiving, administering, and initially monitoring the effects of the medication. The typical acute or ambulatory care medication cycle contains 10–15 independent steps in the process. If the personnel and systems operating within the cycle perform at 99% accuracy, this means that in a 10 to 15-step process, there is a 10–14% error rate. Based on the literature, the Advisory Board Company projects that medication errors and ADEs extract a terrible toll. In an average 400-bed hospital with 15,500 admissions per year and a 6.5% ADE rate, there will be 575 patients per year with significant ADES, 302 patients with serious ADEs, 120 patients with life-threatening ADEs, and 10 patients with fatal ADEs as well as additional costs of $2,318,400 and additional lengths of stay of 2218 days per year.[8]

Any successful reform strategy to decrease medication errors and ADEs must begin with understanding the sources of these medication errors and ADEs within the medication-use cycle as presented in Fig. 1. There are four discrete activities in the medication-use cycle that need reform—physician prescribing, order processing, drug delivery, and reporting and event capture. Forty nine percent of medication errors occur at the ordering stage. Twenty five percent of medication errors occur at the medication processing stage. Twenty six percent of medication errors occur at the medication administration. The largest percentage of preventable ADEs occurs at the physician prescribing stage. Fortunately, the largest percentage of intercepted ADEs also occur at the physician prescribing stage because the physician has the pharmacist, nurse, and patient who can potentially intercept their errors. The lowest percentage of intercepted ADEs occurs at the administration stage of the process because



[1] An ADE that was preventable by any means currently available.

[2] A medication-related incident with the potential for injury that was intercepted before it reached the patient.

[3] A medication-related incident with the potential for injury that reached the patient and did not result in an ADE.

Fig. 1 Incidence of ADEs lends insight to reform strategy. (© 1999 The Advisory Board Company.)

the nurse (or the ambulatory patient by analogy) has no other health care professional to check the final step and possibly catch errors.

Within the medication cycle, there are two basic sources of medication errors and ADEs: systems and humans. It is essential to understand how systems and humans interact to create or prevent medication errors and ADEs and to identify and intervene at potential fail points. Historically, health care organizations have relied heavily on the individual accountability approach

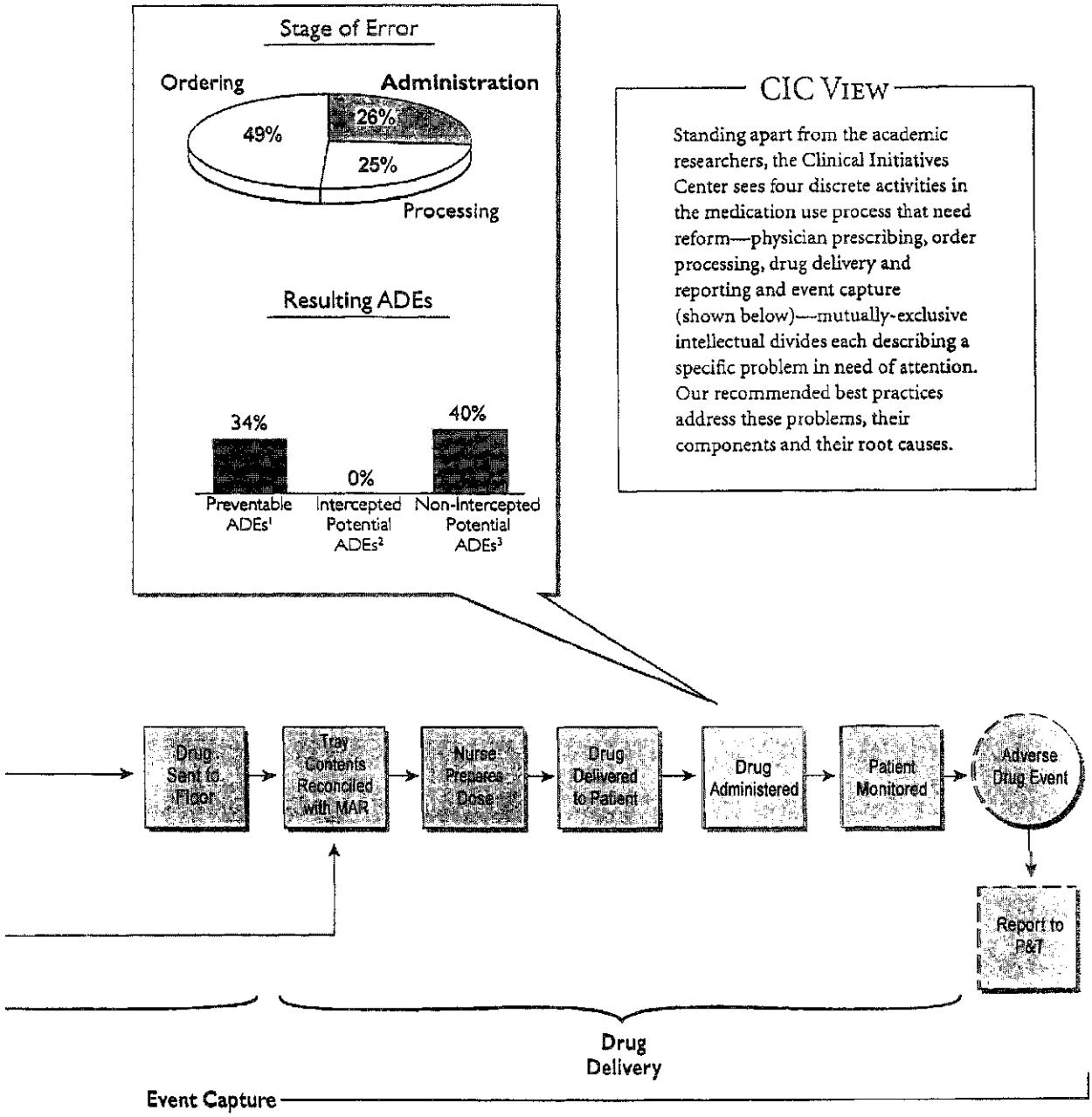


Fig. 1 Incidence of ADEs lends insight to reform strategy. (© 1999 The Advisory Board Company.) (*Continued*).

with elaborate systems for scoring the severity of medication errors and threats of severe punishment. The individual accountability approach focuses on the individual who generated the error or ADE as being fully responsible. The systems' approach focuses on the system failures that set up individuals to generate errors. What is needed is an approach that appropriately integrates individual accountability with systems' enhancements on a continuum that provides reliable, safe care to each patient. The recommended best practices within this article address these problems, their components, and their root causes, as well as point out strategies for identifying and preventing medication errors and ADEs.

SCIENTIFIC INVESTIGATION OF PREVENTABLE PATIENT HARM

Data about preventable medication errors from organizational experience and the literature should be used to improve medication-use systems to enhance patient safety.[9] Each health care organization has a different culture, resources, and priorities, and is at a different evolutionary stage in reaching "best practices." Rather than proposing a rigid, stepwise process for investigating preventable patient harm, readers are encouraged to investigate patient harm in new ways appropriate to their own practice environments. There are no easy solutions, and there is no consensus about how best to prevent medication errors and ADEs. Two inductive approaches to prevention that offer a broader scientific, investigation of patient safety are the process-improvement approach and the outcomes-measurement approach. Other similar techniques, such as root-cause analysis and failure-mode and effects analysis have been discussed elsewhere.[2,4]

The Process-Improvement Approach

The process-improvement approach to system safety evolved from an expert workshop and continuing dialogue on patient safety sponsored by the National Patient Safety Foundation (NPSF).[10] This line of thinking says that study of the ultimate (rather than just the proximate) source of errors and ADEs is needed. Reason[11] first developed the idea that harmful patient outcomes are the result of latent, small degradations within a system com-

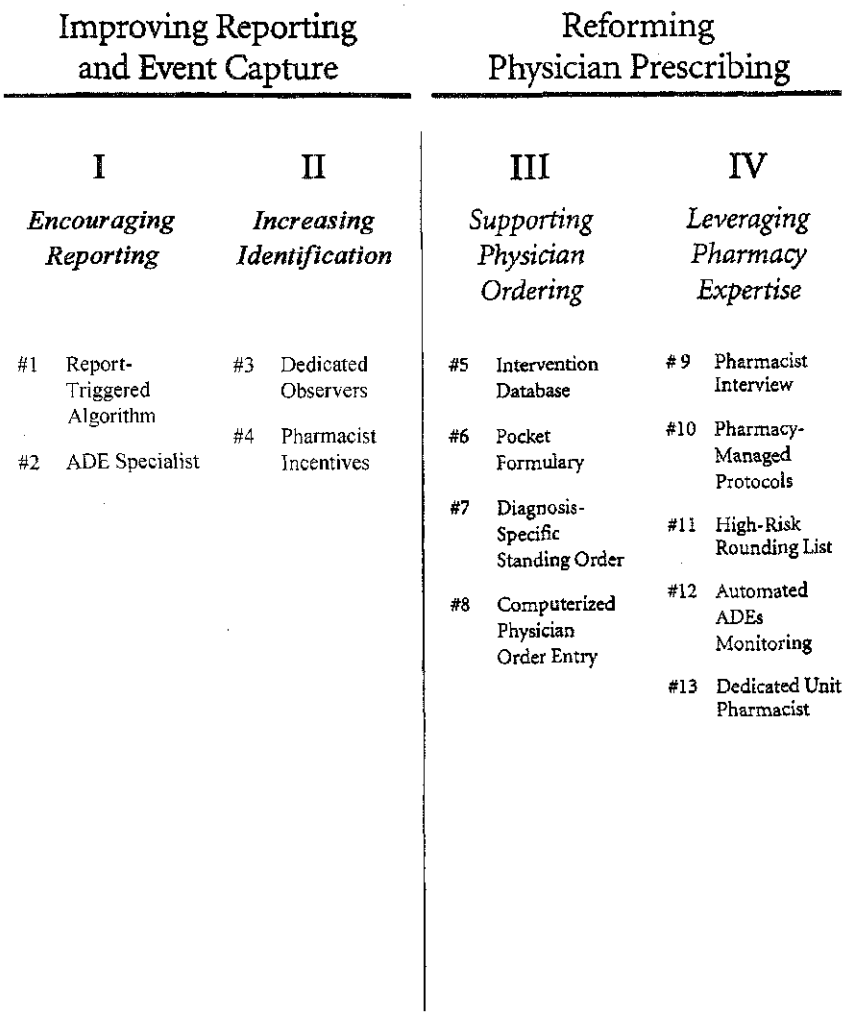


Fig. 2 Identifying and preventing ADEs. (© 1999 The Advisory Board Company.)

bining at some point to cause a harmful patient outcome. The harmful outcome was long in coming and was a natural result of the way the system was designed and operated. According to the process-improvement approach, medication-use is a complex system with many potential points of failure. Each latent point of failure within the system is in itself insufficient to cause an accident (e.g., the sterile-products pharmacist catches an error made by a technician in preparing an intravenous admixture). The pattern of these potential failures is dynamic and depends on the individual elements of the medication-use process.

There is a "sharp end" and a "blunt end" to the medication-use process; both may harbor latent points of failure. The sharp end of the system is where the health care providers are. They interact directly with the medication-use process and are directly exposed to its hazards (e.g., heavy workload, drug supply shortages, paperwork associated with new Medicare compliance regulations). The blunt end of the system is where regulations, new drug technologies, and reimbursement policies are structured, and where many of the competing demands within the system are created. For example, there is a constant competing demand not only to produce care very quickly but also to have it be error free. Despite this competing demand, safe operations are the rule and harmful outcomes are infrequent.

When a visible failure occurs, people focus on evaluating the performance of health care providers. Because the negative outcome is known, this results in a bias toward hindsight in which the events leading to the negative outcome are seen as obvious, even though they may not

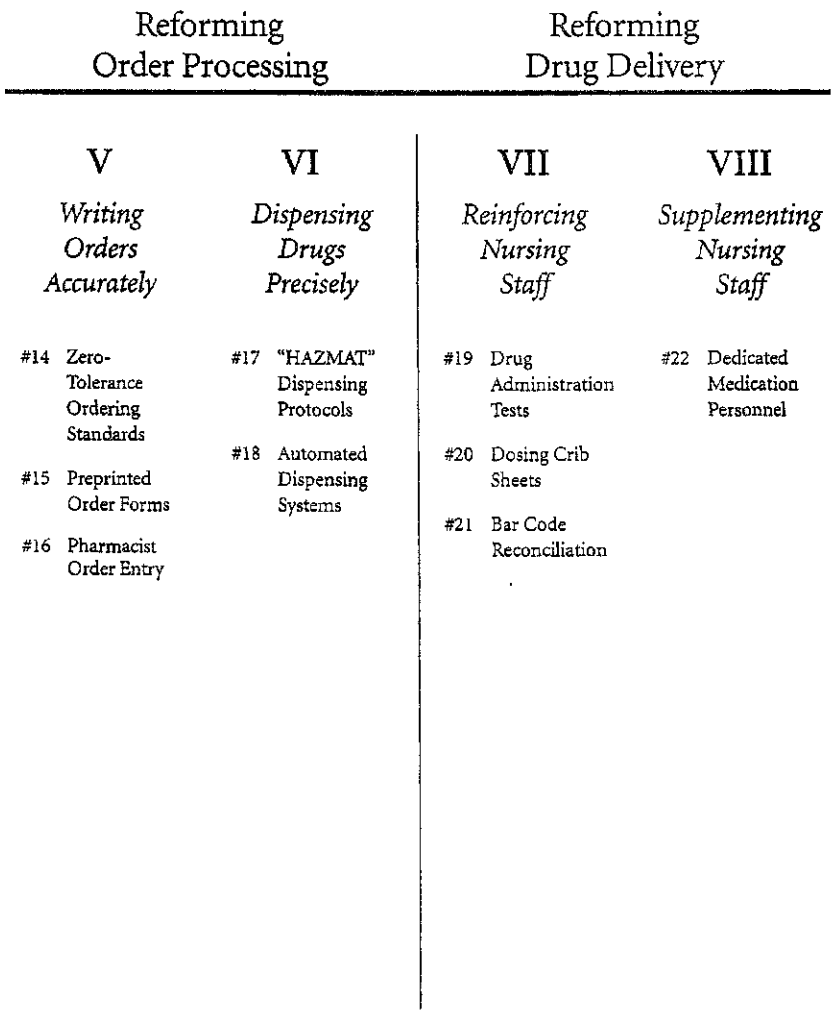


Fig. 2 Identifying and preventing ADEs. (© 1999 The Advisory Board Company.) (*Continued*).

have seemed obvious to the provider at the time of the adverse drug event. Hindsight bias is the greatest obstacle to making personnel performance more robust and resilient in providing patient safety. Retelling of these "celebrated accident" or "first stories" reinforces the view that the provider acted alone in creating the error.

The immediate reaction to celebrated accidents in many health care organizations is to blame the provider and institute new training, rules, technology, and disciplinary actions so that this type of error will never reoccur. Investigation of the harmful outcome then stops. Many of these new changes are not tested thoroughly, add complexity to the already fragile system, and introduce new types of failures; thus, the cycle of harmful outcomes merely repeats itself at different points in the medication-use process. In the case of medication use, the classic celebrated accident occurs when a potentially lethal drug is misused (e.g., a patient receive a dose 10 times too high) and the patient dies as a result. What typically happens next is that restrictions are placed on the use of the offending drug and on the provider's related functions. Unfortunately, these restrictions can keep patients who may benefit from the drug from receiving it in a timely and accurate manner, and can prompt the provider to focus on getting through cumbersome mechanics rather than paying attention to the drug's safe use. Restrictions should be thought of in the context of the entire medication-use process, not just one drug. The thought process should be expanded to include safe handling of other potentially lethal drugs, not just the one that harmed a patient.

Because each step in the medication-use cycle can be associated with preventable medication errors and ADEs, systems must be assessed and enhanced, in their entire scope and each component. Fig. 2 lists 22 examples of strategies for identifying and preventing medication errors and adverse drug events by reforming various components of the medication-use cycle. In addition, in their standards for medication use, the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) recognizes that the multidisciplinary teams must be responsible for all components of the medication-use cycle. Keys to improving reporting and event capture usually result when reporting is nonpunitive or easy to do, or when dedicated resources such as an ADE specialist or observers are in place or incentives are used.[12] Although reporting and event capture can be improved, they will never be perfect. A related and important strategy is to proactively learn from the experience of other organizations. Comparisons can be made with other organizations through such reporting mechanisms as the Institute for Safe Medication Practices (ISMP) Newsletter, FDA Alerts, USP's MedMARx national medications errors database, JCAHO's Sentinel Event Alerts (high-alert medications), and the media. Regardless of whether there is medication error or ADE specific to a health care practice environment or not, if the medication error or ADE is happening elsewhere, it could likely happen at the individual practice site. Examples of preemptive strikes to protect patients from harm include instituting protocols for use, restrictions on the duration or route of therapy, goal setting, education, and feedback procedures, and sometimes even turning down requests for a drug to be added to the formulary.

Because prescribing errors have been identified as a leading cause of preventable medication errors and ADEs, reforming physician prescribing should also be given a high priority. Although computerized physician order entry with clinical decision support would appear ideal, many organizations may not have the information systems infrastructure or funds to accomplish such a goal in the near future. It is generally recognized that leveraging pharmacy expertise is in many cases the most cost-effective way to support physicians in reforming prescribing through a variety of initiatives. Examples of leveraging pharmacy expertise include dedicated unit pharmacists, pharmacy admissions interviews, pharmacy-managed protocols, and pharmacist-led ambulatory care clinics.[2,12,13]

Thus, the process-improvement approach to the safety of the medication-use cycle goes beyond the celebrated cases and first stories to scientifically investigate the system as a whole. Data on near-misses and uncelebrated errors should be analyzed to find hidden flaws and strengths, and to better understand the dynamics of our medication-use system. Scientific investigation of the whole cycle—peeling away the layers of the onion—will reveal latent points of failure and facilitate a redesign that substantially reduces the occurrence of harmful outcomes.[11]

The Outcomes-Measurement Approach

The second scientific approach to prevention focuses on negative patient outcomes (ADEs) rather than on process (medication errors). The outcomes-measurement approach pioneered by Classen[14] views the process-improvement angle as flawed because it does not distinguish between medication errors and ADEs. Although dissecting medication errors may improve patient outcomes, only 1% of all medication errors result in ADEs and 50% of ADEs can be prevented.[14] The extensive studies of the drug-use process and of error prevention have often been done at the expense of demonstrating ways of identifying and preventing ADEs that produce actual patient harm. Improving the system (preventing medication errors) does not necessarily improve patient outcomes or reduce

costs. The outcomes-measurement approach advocates the rigorous study of the epidemiology of actual ADEs, combined with continuous quality improvement techniques and nonpunitive communication to achieve a true impact on patient safety through improved outcomes.

Specifically, the outcomes-measurement approach asserts that rigorous tracking of actual ADEs, coupled with an epidemiologic investigation of their sources, is the foundation for improving patient outcomes through prevention, research, and education. Computerized surveillance systems have already shown great potential to prevent ADEs through such mechanisms as alerts about drug allergies, drug interactions, and inappropriate dosages. Many ADEs result from a lack of integrated information at the point of clinical decision making rather than from carelessness or lack of knowledge.

Measurement of the outcomes of ADEs cannot wait until the health care organization has an electronic medication record or a comprehensive, computerized disease-management surveillance system. An ADE outcomes-prevention project should be selected and implemented. Good tools certainly make measurement faster and easier, but in their absence there are still many outcomes-measurement strategies that can be successfully used to prevent ADEs. Various researchers have studied the causes of ADEs by tracking them to their root causes, even though this was done through an entirely manual system of chart reviews and drug usage evaluations.[13] Common findings of major causes of preventable ADEs were related to dosage errors (e.g., with renally excreted drugs), drug allergies, and initial use of new drugs. Pharmacists can use many drugs with potentially severe adverse effects safely with appropriate monitoring, intervention, and education. Typical examples from the literature or an organization's own ADE-tracking or medical records system might include analyzing the use of antimicrobials in association with ADEs, admissions due to ADEs or visits to ambulatory clinics due to ADEs.[15–19]

Systematic and timely feedback are keys to generating cooperation so that ADEs in progress do not become more severe and can be prevented in the future. Feedback should be communicated in a nonpunitive way to encourage cooperation with and enthusiasm for a program of research, education, and prevention.[20]

Summary

In the process-improvement or outcomes-measurement approaches, medication-use system redesign should 1) identify and assess lynchpin safety components of the medication-use cycle as well as improving event capture and reporting, 2) develop a medication system safety plan through a multidisciplinary team approach with the support from executive management, 3) set priorities and timelines for corrective actions in accordance with the organization's strategic planning and budgeting processes taking into account the cost effectiveness and feasibility of the strategy for the organization, and 4) work through local constraints or risks to provide a safer medication-use system for patients. The process-improvement approach may be more appropriate in a health care practice environment where systems are clearly not providing the safety net they should be. In other organizations, a focus on preventing negative outcomes may provide the best investment in patient safety. Both strategies have validity because processes and outcomes overlap.

ENHANCING HUMAN RELIABILITY

The objective of this section is to introduce readers to the concepts of human reliability in the complex medication-use cycle. It is not intended to replace comprehensive treatments of the discipline of human factors research already available but rather to provide a starting point for readers to view human reliability and specifically human errors in the medication-use cycle from a different and more dynamic perspective.[6,7,11] The study of human reliability gives insights into how health care providers operate under competing demands and time limits in caring for patients. There are many factors affecting human reliability. Some factors move human reliability toward 100%, while others drive it away[7] (Fig. 3). Human reliability never reaches 100% all the time but knowing what influences human behavior to become more reliable can be used to develop added strategies to

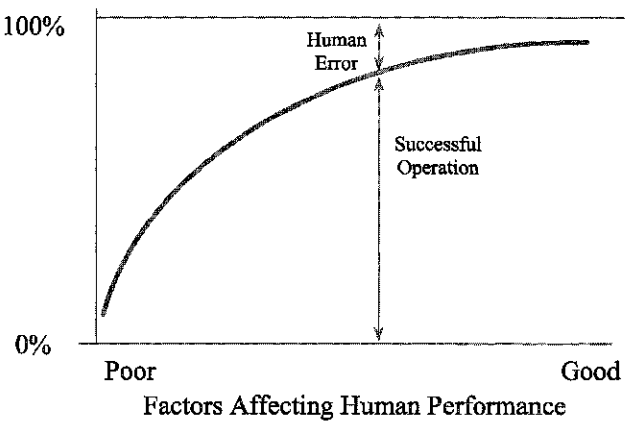


Fig. 3 Human reliability curve. (From Ref. [7].)

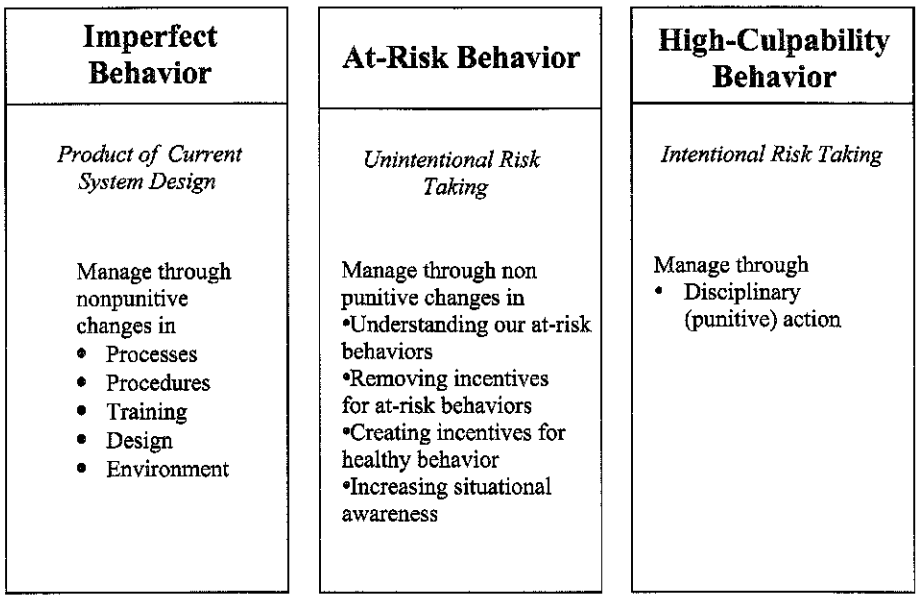


Fig. 4 Three manageable behaviors. (From Ref. [7].)

reduce medication errors and ADEs. Three types of human behavior influence human reliability and thus can be used to expand the approaches to reducing medication errors and associated ADEs[7] (Fig. 4).

Imperfect Behavior

The first aspect of human reliability focuses on situations where humans can not produce 100% reliability all the time. Although we cannot change our nature as humans, we can change the medication-use system in which we work. Imperfect behavior is the product of systems design. The classic example is physician handwritten medication orders that are often illegible or incomplete. This is a system designed to produce errors. It is natural or normal for errors to occur with this "as-designed" system. For the average physician, pharmacist, nurse, or patient, quality and safety fail when the medication-use system fails. The approach to decreasing imperfect behavior and increasing human reliability is to identify and change those system factors that negatively affect human reliability. These system factors fall into four categories: people, environment, actions, resources. Human system analysis includes such factors as knowledge, skills, physical capability, adaptability, and fallibility. Environmental system analysis includes such factors as temperature, noise, light, peer communication, facility layout and location, and management/labor relations. Action systems analysis include factors such as task design, technology and information management, work measurement and methods improvement, and policies and procedures. Resource system analysis includes such factors as tools, equipment, support from others, and time. In exhibiting imperfect behavior, health care providers are trying to do their best, are not engaging in risk-taking behavior, and are in a situation where their human reliability or performance is shaped by the system in which they operate. Thus, solutions to imperfect behavior decreasing human reliability are not disciplinary or punitive but are systems analysis and redesign oriented.

At-Risk Behavior

The second aspect of human reliability focuses on situations where humans unintentionally engage in risk taking. At-risk behavior means that intentional conduct unintentionally results in creating a significant and unjustifiable risk that may cause an undesirable outcome. The classic example of this is the need for the health care provider to provide patient care simultaneously, both quickly and accurately under conditions of competing demands and time limits. There are three at-risk cognitive factors affecting human reliability (both expertise and error) within the medication-use cycle: knowledge factors, attentional dynamics, and strategic factors.[21]

Knowledge factors are the types of knowledge that are available to solve problems as they arise in the medi-

cation-use process. It is normal for health care providers to adopt a limited number of strategies to deal with processes or routine variations within the medication-use process. However, when an unusual or surprising situation presents itself, the relevant knowledge may be inadequate, imprecise, or too simplified. For example, risks of new drug therapy are not always perfectly predictable, because drugs are tested in a small subset of the general population. Known adverse effects do not occur in all patients given the new drug. In many cases, it is easier to see the benefits the patient could receive from the drug than to determine the risks associated with the drug.

Attentional dynamics are how humans control and manage the mental workload as circumstances develop and change over time. The mind can pay attention to only so many situations at a time, so attention shifts as events occur. If a situation comes to light that does not agree with what is expected, attention usually shifts to investigate. An ICU patient often receives numerous intravenous medications. If the wrong one is infused (e.g., a vasopressor), the patient would receive an incorrect drug and suffer the consequences. The responding health care providers might not immediately discern that the wrong drug was infusing. The providers would probably focus their attention on whatever seemed necessary to address the patient's adverse reaction (e.g., lowering the blood pressure) even though the source of the event was not known. Humans are great at recovery after an event, even when their lack of attention might have been the source of the problem.

Strategic factors are how humans deal with situations when conflicting goals are present and the best course of action is not readily apparent (because, for example, of limited resources and the need to act immediately). The health care provider must decide whether to act immediately with inadequate information, to wait for more information to be become available, or to consider other alternatives. This may result in the misapplication of usually good guidelines. In hindsight (after all the strategic factors are known), the decision made as the situation evolves often appear to be reckless. If a pharmacist receives five critical orders simultaneously, then he/she must decide which one to fill first or to call for help. The pharmacist must decide whether to dispense the drugs immediately or first check a suspiciously high dose in relationship to other variables when the values are not immediately available. If the pharmacist dispenses the suspiciously high doses and the patient's outcome is positive, the dispensing will be reviewed as uneventful even though the safety margin was reduced. However, if the outcome is negative, the pharmacist may be seen as reckless and having made an error.

Thus, attributes of at-risk behavior are judged against a specific outcome, judged risky by an external observer, involve a choice between different behaviors, are not understood to be of significant or unjustifiable risk by the health care provider taking the risk, and are generally considered more blameworthy than system-induced or imperfect behavior errors.

The approach to decreasing at-risk behavior and increasing human reliability is to change incentives so those safe behaviors are chosen over at-risk behaviors. In health care systems where mediation-use systems already have appropriate checks and balances, changing at-risk behaviors represents the largest opportunity for safety and quality gains since medication errors and ADEs are often side effects of weak cognitive functions. The analysis and corrective actions should include 1) creating a tally sheet of incentives for comparison of safe behaviors with at-risk behaviors for a specific function or area in the medication-use cycle so that safe behavior can be compared with at-risk behavior, 2) rate each incentive as strong or weak, and 3) modify incentives to change behavior. It is essential to recognize that the strength of safe or at-risk behaviors is influenced by the following factors: 1) certain consequences are stronger than uncertain consequences, 2) consequences are stronger than policies and procedures or other environmental factors, and 3) immediate consequences are stronger than delayed consequences. In exhibiting at-risk behavior, the health care provider's conduct is intentional but they do not understand that the conduct itself significantly increases the risk of a negative consequence, and is a situation where their human reliability or performance is shaped by expediency and at-risk incentives rather than safe practices and potential consequences. The health care provider may be negligent in that they should have been aware of a substantial and unjustifiable risk and under the law may be required to provide compensation. However, for the health care organization, the solutions to at-risk behavior decreasing human reliability are not disciplinary or punitive but are incentive oriented. Punitive sanctions are an obstacle to other initiatives such as event reporting.[7] Correct solutions to at-risk behaviors include such things as enhanced management–front line worker communication and direction, increased health care team training versus just technical or professional training, and consistent errors management awareness.

High-Culpability Behavior

The third aspect of human reliability focuses on situations where humans intentionally engage in risk taking. High-culpability behavior means that the person

consciously disregarded the fact that their conduct would significantly and unjustifiably increase the risk that negative consequences would occur. The risk must be of such a nature and degree that, considering the circumstances known to the healthcare provider, its disregard involves a gross deviation from the standard of care that a reasonable employee would observe in his situation. The approach to decreasing high-culpability behavior is disciplinary or punitive because high-culpability behavior must be changed or the person cannot continue to function as a healthcare provider. High-culpability behavior is the single behavior where punitive sanctions should be considered as a solution.[7] Punitive strategies may include such things as progressive disciplinary actions, time off, punitive training or duties, and even termination.

In summary, human nature can not be changed, but the changing the circumstances under which it operates in the medication-use process can enhance human reliability. Traditional responses to a medication error and resultant patient harm include discipline, new rules, retraining, technology, or environmental changes. These responses have a place but they address symptoms rather than trying to understand human reliability. Unfortunately, most of the time traditional responses have assumed that human recklessness or high-culpability behavior was the root cause of the error when it was not. Traditional approaches have sought to regiment, rather than enhance human reliability. Preventable medication errors and ADEs happen because of reliance on weak human cognition and reliability. Strategies that seek to minimize human error (e.g., adding additional procedures and steps) can often make the system more prone to medication errors and ADEs at other points, even though the intention was exactly the opposite. Strategies designed to enhance human reliability have a higher probability of making the medication-use cycle safer for patients. Much effort has been put into improving processes and outcomes in the medication-use system, but human reliability has been largely ignored. Successful preventive strategies must take into account human abilities and limitations, and will use these strategies to correct for the limitations, and to enhance the abilities.

THE ROLE OF THE PHARMACIST

The IOM Report has given health care a clear mandate to make the medication-use cycle safer and has given pharmacists a clear opportunity to shine. Pharmacists must have an unwavering commitment to the priority of preventing medication errors and ADEs. Now is a significant time to be in the pharmacy profession and pharmacists should act the part. The following practice management guidelines are presented as a practical approach by which pharmacists can shape their own practice environments to decrease medication errors and ADEs and increase patient safety. Medication quality only begins when patient safety begins. Therefore, medication safety strategies should be an essential part of evidence-based medicine practices.

Practice management guideline #1: Make medication safety improvement a pharmacy leadership priority. Every recent treatise on error management recognizes leveraging pharmacy expertise as an essential key in preventing medication errors and ADEs. A multidisciplinary medication safety team and a 5-year medication safety plan should be part of every pharmacy department or health care team's strategic plan. As the drug therapy experts, pharmacists should be in leadership positions to create medication cultures of safety.

Practice management guideline #2: Stop using the medication error reporting system primarily for punishment and shift the emphasis to using reporting for improvement. Instead, help to create an environment in which fear may be alleviated in large part by creating an open and safe environment for detecting, reporting, and investigating how errors and ADEs occur so they can be reduced in the future. Extend the collegial peer review process of morbidity and mortality conferences to the context of improving medication safety. There has been a great deal of erosion of trust, and it is exceedingly difficult to have a high-performance organization without having a high-trust organization.

Practice management guideline #3: Initiate and maintain ongoing self-assessments of the safety of individual clinical practices as well as with the health care team, the pharmacy department, and the organization. Use the learning experiences of others and self to proactively implement known "best practices" locally to prevent medication errors and to develop your own safety audit tools. Be dissatisfied with the status quo and seek to develop an error management vision and then take the practical first steps to implement it.

Practice management guideline #4: Be accountable for medication safety by designing, implementing, and maintaining safe practices in the medication-use cycle. This might include such things as educating patients and their families regarding appropriate use of their medications, using protocols for the use of potentially lethal or

narrow therapeutic index drugs, insisting that pharmacy (not nursing) prepare all intravenous admixtures, and implementing technology, automation, and information support systems that enhance the frontline pharmacist's ability to care for patients.

Practice management guideline #5: Integrate medication safety understanding into all pharmacist, technician, resident, student training continuing education, and evaluations. Ensure that everyone understands that medication safety is everyone's business and everyone has a role in keeping patients safe. If the messenger aide does not understand the importance of delivering the needed intravenous admixture to the right patient care area on time, everything that the clinical specialist did in customizing the drug therapy and the staff pharmacist in reviewing the medication profile and preparing the order can become academic.

Practice management guideline #6: Realize that competing priorities and severe financial constraints are the environment in which health care organizations operate today. If the organization needs to improve revenues or margins by a certain percentage, can the pharmacist quantify how medication error and ADE prevention contribute to the financial goal? Further, can the pharmacist demonstrate why the health care organization should shift limited resources to medication error management over some other worthy and cost-effective goal? Demonstration of a positive impact on patient outcomes and health care costs is a prerequisite to getting needed resources for medication safety, but it is not a guarantee. Financial constraints and competing priorities are perhaps the most daunting challenge, but they are also simultaneously the greatest opportunity.

Practice management guideline #7: Make medication safety research a priority. How can technology and information management be deployed to make the medication-use cycle safer and position pharmacists to better care for patients? How will gene therapy affect the demand for traditional drug therapies, and will pharmacists be in the forefront of safely managing gene therapy? Intuitively, medication error and ADE prevention should result in better financial, clinical, and humanistic outcomes, but added meaningful outcomes measurement and research are needed to validate that business costs rise significantly with poor quality and safety. If pharmacists do not make medication safety research a priority, it is likely that this role will be filled by other health care providers, regulatory agencies, or even sophisticated information systems.

The urgent need to enhance the safety of drug therapy shows that the medication-use cycle must change. Pharmacists as the drug therapy experts are positioned to shape their practice environments to focus attention on a critical set of priorities to enhance the medication-use cycle to better serve patient welfare and safety.

CONCLUSION

Much of the knowledge developed about medication errors and ADEs has depended on the ability of individual pharmacists to detect problems and take an active part in resolving them. The increasing use of complex medication regimens has drawn attention to the number of iatrogenic medication errors and ADEs, as well as their associated costs. Pharmacists must work to reduce predisposing factors so that safety can be enhanced and costs reduced. A new practice model as an adjunct to evidence-based medicine practices must be created to prevent medication errors and ADEs, and to let others outside the pharmacy know that we are ready to lend our expertise and energy to this critical endeavor.

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Medication Use Evaluation

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INTRODUCTION

A Medication Use Evaluation (MUE), or Drug Use Evaluation (DUE) program is a planned, criteria-based systematic process for monitoring, evaluating, and continually improving medication use, with the ultimate aim of improving medication-related outcomes for a group of patients or consumers. The improvement process that is MUE has application in all settings where pharmaceutical care is provided. Its focus is on assessing and improving one or more of the steps involved in medication use (patient assessment, prescribing, preparation and dispensing, administration, patient monitoring for medication safety and efficacy, and patient education). Practitioners in different settings may use a variety of terms to describe interventions that fall under the lexicon of MUE, including drug utilization review, drug usage review, drug use review, drug use evaluation, and drug utilization evaluation. MUE overlaps with the provision of pharmaceutical care when a pharmacist uses criteria, therapeutic guidelines or clinical pathways to identify, resolve, and prevent medication-related problems and guide the care for an individual patient.

DEFINITIONS

An audit (or study) is a single evaluation (data collection and assessment) focusing on a particular medication, drug class, disease state, or process. Typically, information is collected, organized, analyzed, and reported to measure current practice. Changes ("corrective actions") are then made, as needed, to address identified concerns and improve care. Individual audits are sometimes erroneously referred to as "an MUE" or "a DUE." Because a one-time project will have minimal impact, audits are only one small component of a comprehensive MUE program.[1]

Criteria are used to measure the quality of medication use. Criteria have been defined as "predetermined elements against which aspects of the quality of a medical service may be compared."[2] Criteria reflect the standard of practice and, therefore, should be current, literature-based, and objective (explicit) rather than subjective (implicit).

Drug regimen review (DRR) is the concurrent review of an individual patient's medication regimen at regular intervals, designed to identify and resolve potential medication-related problems. This pharmaceutical care process is typically guided by the pharmacist's personal judgement, rather than explicit criteria. Monthly drug regimen review by a pharmacist is required for patients in U.S. nursing homes. Reviewing the appropriateness of a new prescription at the time of dispensing (in the context of the patient's overall medication profile) is a DRR activity. This type of drug regimen review is referred to in the Federal Omnibus Budget Reconciliation Act of 1990 (OBRA '90) regulations[3] and certain state pharmacy practice acts as prospective drug use review (DUR). When the pharmacist uses organizationally sanctioned criteria to guide individual patient evaluations and collects data on the results, this care becomes part of the MUE process.

Drug utilization review or drug-use review (DUR) has been defined as "a formal program for assessing data on drug use against explicit, prospective standards, and, as necessary, introducing remedial strategies to achieve some desired end."[4] Traditionally, many DUR audits have been retrospective in approach, such as computerized evaluations of large databases maintained by insurers or pharmacy benefit organizations. While most experts agree there is little difference among the processes when implemented fully, a number of professional groups now prefer to use the term "Medication Use Evaluation"[5] or "Drug Use Evaluation,"[6] rather than DUR.

Indicators provide a "quantitative measure of an aspect of patient care that can be used in monitoring, evaluating, and improving the quality and appropriateness of healthcare delivery."[7] An indicator may serve as a screen or "red flag" to identify a potential problem (postoperative infection rate, number of serious medication errors) or measure progress toward an established goal (percent of patients with atrial fibrillation who are anticoagulated).

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GOALS OF MUE

Within the overall goal of improving medication-related outcomes, an MUE program can have a number of more specific aims. These include improving the efficiency and effectiveness of medication use, promoting medication safety, increasing patient satisfaction, supporting a formulary system, and controlling treatment costs while optimizing care.

ROLE OF PHARMACIST AND OTHERS

Because the medication-use process involves complex steps and interactions among a number of healthcare professionals and caregivers, an MUE program must be the responsibility of the entire organization and an interdisciplinary approach must be used, involving physicians and other prescribers, nurses, pharmacists, administrators, and (ideally) patients or consumers. Other healthcare personnel should contribute their unique perspectives and skills when the evaluation and improvement process addresses their area of responsibility. Pharmacists, by virtue of their expertise and their mission of ensuring optimal patient outcomes,[8] should exert leadership and work collaboratively with other members of the health care team in the ongoing process of medication use improvement through MUE. Having physician champions for the improvement process can make or break the success of an MUE program.[9,10]

SCOPE

An MUE program must be comprehensive, with the goal of impacting all the patients served by an organization or institution. The target population, therefore, could be all the patients at a single ambulatory pharmacy or hospital, within a healthcare system, the "covered lives" managed by a health maintenance organization or insurer, or enrollees in a government program such as Medicaid. To benefit the overall population, one initial step should be to define the types of patients (ages, most prevalent disease states, medication utilization, and unmet needs) and settings (acute care, ambulatory, long-term care, home care, etc.) under the purview of an MUE program.

PRIORITY SETTING

Once the scope of an MUE program has been determined, priorities should be set for evaluation and improvement activities. This simply involves identifying where the greatest positive impact can be achieved by allocating resources, either to correct identified problems or to identify and improve less-than-optimal practices. To make the best use of existing resources, an MUE program may be limited to three to five major initiatives at one time or could encompass a large number of concurrent initiatives. Selected topics could vary widely based on the characteristics of the organization and patients involved.

Some common ways of setting priorities are to focus on medications, drug classes, disease states, or processes that are:

1. *High risk*: Medications, procedures, processes, and disease states for which there is a greater chance for adverse outcomes (e.g., chemotherapy administration, intravenous potassium use, intrathecal injections, anticoagulation, medications with a narrow therapeutic index, and care of immunocompromised patients).
2. *High use/high volume*: Those medications used most frequently, as well as the most common procedures and disease states. Incremental improvements made in these areas will impact the greatest number of patients (e.g., antibiotic use, pain management, acetaminophen, community-acquired pneumonia, otitis media, and patient counseling).
3. *High cost*: High-cost medications and procedures are often targeted for intervention, because wasted resources divert funds from more beneficial patient care and have a negative financial impact on the organization.
4. *Associated with high risk patient groups*: These include infants and children, the elderly, and patients with organ dysfunction or cancer. By targeting populations that are more prone to adverse effects or treatment problems, a number of important issues or medications can be addressed at the same time.
5. *"Problem-prone"*: These are areas identified either by local surveillance or based on medical literature findings. An organization may label an issue "problem-prone" if outcomes are worse than national benchmarks or standards (e.g., a postoperative infection rate of 5%) or prior efforts have not reached their goals. Thought leaders and national publications frequently highlight issues that are expected to be problematic in most organizations (such as antimicrobial resistance, overuse of vancomycin, or inadequate pain management).

It is helpful to get organization-wide consensus on the priorities for medication use improvement. Issues that fall into more than one category, for example, frequent and high risk or problem-prone, should be addressed or evaluated first.

STEPS IN THE MUE PROCESS

In its simplest form, the MUE process is an ongoing improvement cycle with no set beginning or end. For each identified high-priority issue, there are four major action steps:

1. *Identify or determine the standard of care or optimal use*: Therapeutic guidelines and consensus documents and standards established by national professional organizations or governmental groups often define ideal processes and outcome goals. Healthcare organizations may adopt national guidelines, or adapt them for local use. An evidence-based medicine approach can also be used to develop guidelines or clinical pathways to meet local needs. It is important to gain consensus from practitioners who will utilize guidelines as part of the implementation process. Ideally, guidelines and protocols should be shared across an organization to encourage implementation before current practices are evaluated.
2. *Data collection (compare actual to optimal)*: This step is the "evaluation," where performance is measured against objective criteria for the processes or outcomes of care. Criteria may relate to indications (for selection of a particular medication or procedure), processes (drug dosing and administration, patient assessment and monitoring) or outcome measures (cure, relief of symptoms, treatment failure, adverse drug event, patient satisfaction).
3. *Intervene*: If indicated, corrective actions should be taken to improve processes, practices, or medication use. Possible actions include the development of consensus statements or guidelines when they do not already exist, providing feedback on performance, education of health professionals (seminars, newsletters, feedback letters, one-on-one communication), creation of tools to support use of guidelines and treatment protocols (such as standard order sets, computerized pathways, pocket cards), redesigned processes, or patient education.
4. *Evaluate the impact of the intervention*: Additional data collection or ongoing monitoring to ensure corrective actions had the desired impact (document improvement) and to guide subsequent incremental steps if further improvement is needed.

To be most effective, a majority of MUE program resources need to be devoted to education and process improvement, rather than measurement and simple data collection. An additional important component is regular (at least annual) evaluation of the overall MUE program to assess its value and improve the MUE process.

APPROACHES TO EVALUATION

Assessments of medication use can be performed through a concurrent, retrospective, or prospective study design (or a combination of these approaches). Each type has advantages and disadvantages.

Retrospective review is conducted after the patient has received a medication, and the treatment is complete. Medical charts or computerized records are screened to identify patterns and trends. This may be the simplest type to perform, because large amounts of data can be reviewed quickly, and the outcomes are known. Information gained from large retrospective reviews is helpful for problem identification and initiating actions that will benefit future patients. However, inaccurate or incomplete documentation could limit the usefulness of information collected.

Concurrent review is performed during the course of treatment and often involves ongoing monitoring of drug therapy. Concurrent evaluation gives pharmacists the opportunity to intervene if potential problems are detected, and thus, current patients can benefit. This type of review also allows additional information to be collected if documentation is incomplete (such as querying prescribers, observing behavior, or interviewing patients). The concurrent approach can be integrated with case management or ongoing pharmacist monitoring activities. It may be more time-consuming if data is collected on individual patients over time. Furthermore, if outcome data is required, it may be months or years before outcomes are known and data collection can be completed.

Prospective review takes place before medication use, and thus, its usual focus is on patient assessment and prescribing. This approach to evaluation can detect and resolve potential problems in individual patients before they occur. Pharmacists routinely perform prospective reviews when assessing new medication orders for possible drug interactions, accurate dosing, or duplicate therapy. Data collection occurs at only one point in time and can easily be integrated with daily pharmacist care activities. However, while data collection for a single pa-

tient may not be very time-consuming, it can take a long time for data to be collected on enough patients to draw conclusions and guide improvement efforts.

TOOLS AND RESOURCES

The professional literature, national treatment guidelines, and locally developed protocols provide key resources for the development of MUE criteria. Various professional groups as well as private businesses also produce medication-specific, disease-specific, or process-oriented criteria that can be adapted for local use.[11–13]

Performance measurement systems, such as the HEDIS® (Health Plan Employer Data and Information Set) managed by the National Committee for Quality Assurance (NCQA)[14] and the ORYX Initiative of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[15] provide indicators for identifying concerns and monitoring the impact of improvement initiatives. In Australia, the government is developing a searchable database of major quality use of medications (QUM) initiatives as a means of sharing resources and ideas.[16]

Computerized databases (such as insurance billing files or electronic medical records) greatly improve the ability to gather and evaluate information compared to manual data collection (e.g., chart reviews). Computer software programs, including proprietary software designed specifically for MUE functions, may be helpful in managing data and reporting.

VALUE OF MUE

The key to MUE is not the "drug use review" or "evaluation" but the improvement process that is guided by the information learned about medication use. The MUE program can be an important tool for gaining professional consensus and focusing organizational energy on activities that will improve medication-related outcomes. An MUE program can be used to integrate a number of important medication improvement initiatives, such as the formulary system, adverse drug reaction reporting, medication error prevention, pharmacist interventions, and other clinical pharmacy services.

LIMITATIONS AND PITFALLS OF MUE

According to critics, the way DUE was practiced in many institutions might better be described as "Don't Use Expensively" or "Don't Use Ever,"[17] because the focus became punitive actions against individual practitioners with a focus on cost control rather than quality improvement. To have legitimacy within the organization, the emphasis must be on actions that truly improve outcomes for patients. The MUE program must have both the administrative authority to promote positive change and support ("buy-in") from practitioners at every level. One important consideration is to avoid using words that imply control or a loss of professional autonomy, because these can be threatening to practicing physicians. Rather than labeling an action "appropriate" (with the connotation of condescending approval or disapproval), state that it is "consistent with the published literature" or "meets Medical Staff-approved criteria"; use "evaluation" rather than "enforcement" and "consult" or "inform" instead of planning an "intervention."[18]

Because evidence-based medicine is an evolving discipline, and the state of knowledge is constantly changing, guidelines must be frequently updated. Indicators, criteria, and even process improvements need to be reassessed to ensure they remain valid.

Often, an MUE program commits to too many initiatives, resulting in insufficient time and energy to complete any of the projects. Follow-through is essential when corrective actions are implemented-the impact must be assessed and adjustments made if needed. If an MUE program becomes authoritarian, bureaucratic, emphasizes analysis of data rather than action, or loses sight of its mission to improve care, it will be ineffective. MUE must be seen as a tool or means to foster improved medication use processes and safer, more effective medication use, rather than an end in itself. Achieving and maintaining improvement requires not only streamlining systems and processes, but also changing the behavior of healthcare practitioners and patients—a difficult proposition.

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Medication Use for Unapproved Indications

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INTRODUCTION

Prescribing drugs for "unapproved" uses is common. The American Medical Association (AMA) estimates that 40%–60% of all prescriptions in the United States are written for drugs being used for something other than their approved purpose.[1] The term *unapproved uses* actually has no legal meaning. An unapproved use merely indicates a lack of Food and Drug Administration (FDA) approval and does not imply an improper or illegal use. Unlabeled use is a more appropriate term and is defined as the use of a drug product in doses, patient populations, routes of administration, or for indications that are not included in FDA-approved product labeling.[2]

With each new prescription or physician order, the pharmacist must decide if the chosen therapy is appropriate for the patient and if there is evidence to support the use of the prescribed drug for the specific indication. How does the pharmacist make this decision when the drug has been prescribed for an unlabeled indication? What is the pharmacist's liability? Will this affect reimbursement?

To address these questions, a Medline search and literature review was performed using the terms unapproved, nonapproved, not approved, unlabeled, off-label, unindicated, and not indicated. A large number of articles, many of which centered around changes in legislation, were found written by or for physicians. Only a handful of articles specifically addressed unlabeled medication use from a pharmacist perspective. This article begins with a brief review of contributing factors to unlabeled medication use and then highlights its frequent occurrence. The remaining sections focus on patient safety and product efficacy, pharmacist liability, and reimbursement issues for unlabeled medication uses. For each section, information found in the literature review is summarized, followed by implications for clinical pharmacy practice.

BACKGROUND AND FREQUENCY

The FDA approves drugs based on large, randomized, well-designed studies that show a product is safe and effective for a specific indication. Once a product is approved and marketed, many other uses can emerge from postmarketing experience. The manufacturer may apply for FDA approval of these additional uses if the patient population is large enough to support the time and expense of more clinical trials. Regardless of labeling, however, the Food, Drug, and Cosmetic Act does not limit the manner in which a physician may use an approved drug. Therefore, once a drug is approved for any indication, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling.[3]

Surveys indicate that 88%–100% of physicians prescribe drugs for unlabeled indications with 25% prescribing for an unlabeled indication daily.[4,5] Published reports, although few in number, reflect a similar occurrence of unlabeled medication use in pharmacy practice. Based on the published studies, chart reviews, and surveys, drug use for unlabeled indications is especially common in the areas of obstetrics, oncology, pediatrics, psychiatry, and infectious diseases (Table 1). Depending on the practice area, patient population, and drug being evaluated, 9%–100% of patients received a medication for an unlabeled use.

PATIENT SAFETY AND PRODUCT EFFICACY

There is a danger that many unlabeled uses are derived from inadequately controlled or uncontrolled studies and anecdotal reports. Two articles reviewing the unlabeled uses of intravenous immunoglobulin (IVIG) evaluated the level of evidence supporting these uses. In the first study,[6] only one-third of the unlabeled uses of IVIG was supported by randomized controlled trials. The other two-thirds were derived from case reports and uncontrolled trials. The second study showed that a substantial proportion of the unlabeled use of IVIG was not even supported by evidence-based guidelines.[7] The authors concluded that it would be prudent to discourage indiscriminate unlabeled uses of IVIG because of the product's unproven clinical effectiveness in unlabeled situations. As Dr. Arnold Relman, editor emeritus of the

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Table 1 Frequency of drug use for unlabeled indications

Practice area	Drug(s) evaluated	Unlabeled Use (%)	
		Patients	Prescriptions
Family Practice [18]	Various	9	NR
Hospital [19]	Metoclopramide	100	100
Infectious Disease [20]	HIV*	81	40
Infectious Disease [7]	IVIG	52	29–100
Obstetrics [21]	Various	23	NR
Oncology [16]	Antineoplastics	56	35
Pediatrics [22]	Ondansetron	NR	12–73
Pediatrics [23]	Various	92	66
Pediatrics [24]	Various	36	18
Pediatrics [25]	Various	NR	7
Psychiatry [26]	Antipsychotics	67	NR

*Drugs used to treat human immunodeficiency virus and its clinical manifestations.
NR = not reported, IVIG = intravenous immunoglobulin.

New England Journal of Medicine has pointed out, "publication of an article on the unapproved use of a drug in a peer-reviewed journal is no guarantee of safety or efficacy."[8] However, in some clinical situations, such as pediatrics, unlabeled uses may be rational and represent the most appropriate treatment for optimal patient care.

When the unlabeled use of an approved drug endangers the public health, the FDA is obligated to investigate thoroughly and to take whatever action is warranted to protect the public. The FDA can require a change in the labeling to warn against the unlabeled use, seek evidence to substantiate the use, restrict the channel of distribution, and even withdraw approval of the drug and remove it from the market. In such instances, the official labeling may include a prominently displayed "box warning" to alert practitioners that certain uses are hazardous and, in effect "disapproved."[9]

Implications for Pharmacists

The American Society of Health-System Pharmacists states that pharmacist should serve as patient advocates and drug information specialists concerning unlabeled uses of medications.[10] Pharmacists must evaluate the available information to assess product efficacy and patient safety. Therefore, pharmacists must have access to accurate and unbiased information about unlabeled uses of prescription drugs. The following textbooks are recognized as authoritative sources on unlabeled uses by the FDA, Blue Cross/Blue Shield, and the Health Insurance Association of America: 1) *The American Hospital Formulary Service Drug Information* (AHFS DI); 2) *The American Medical Association Drug Evaluations* (AMA DE); and 3) *The United States Pharmacopeial Drug Information* (USP DI). The information in AHFS DI is derived from published medical literature, as well as scientific meetings, educational programs, professional interactions, and comments provided by editorial reviewers. Not all unlabeled uses included in AHFS DI are well established. Some unlabeled uses may be acceptable but are considered investigational because of limited experience. Unlabeled uses listed in the USP DI are selected by USP Advisory Panels based on current literature, current prescribing, and utilization practices. The AMA DE is no longer published, but its contents have been incorporated into USP DI. None of these authoritative textbooks include references.

Additional resources that pharmacists can use for information about unlabeled indications include medical and pharmacy textbooks, handbooks, journals, electronic databases, and the Internet. Although the Internet can be a useful resource for finding information, many sites offer unreferenced information, often with unsubstantiated claims. Drug information services staffed by pharmacists trained in the retrieval, interpretation, and dissemination of medical literature are excellent resources for determining if an unlabeled use of a drug is appropriate.

Another concern for pharmacists is manufacturers' distribution of information on unlabeled drug uses. The FDA Modernization Act passed by Congress in 1997 allows pharmaceutical companies to distribute reprints of

peer-reviewed journal articles or reference textbooks that include information about unlabeled uses of their products to health care practitioners.[11,12] The FDA does not include pharmacists as "health care practitioners" thus limiting access to information about unlabeled indications disseminated by the pharmaceutical companies to physicians. Pharmacists can and should gain access to this and other information using the drug information resources discussed previously. It is important to perform a comprehensive review of all information available on the unlabeled uses of a medication and to not determine product efficacy or patient safety on the basis of a single source.

LIABILITY

Dispensing a medication for an unlabeled use, dose, or dosage form does not violate federal law. In fact, to date, no pharmacist is known to have been prosecuted for dispensing a product for an unlabeled use. However, a deviation from the safe and effective guidelines provided in the product labeling does expose the pharmacist to some liability. A pharmacist may be subject to malpractice action if patient injury results from the administration of a medication for an unlabeled use.[13,14]

Lack of criminal prosecution is not a predictor of future actions or exposure to civil litigation. Therefore, it is important for a pharmacist to be familiar with labeled indications and unlabeled uses of a drug and to be prepared to defend the appropriateness of a drug's use in the event of litigation.[3] Liability will be minimized if the pharmacist, in the exercise of sound professional judgment, concludes that the use is rational, safe, and reasonable.[13]

In addition, a patient is entitled to know when a drug is used for an unlabeled use. It is reasonable for the physician or pharmacist to inform the patient that the drug's use is not FDA approved, it is safe and effective for other uses, and some data exist to support its unlabeled use. Such discussions should be documented in the patient's medical record.[12] A consent form signed by the patient is highly recommended but is not currently necessary if the drug is used in the normal practice of medicine.[9,12]

REIMBURSEMENT

Reimbursement for unlabeled uses of drugs has become an important medical and financial issue. Decisions on coverage for drug therapy are complicated because it is often difficult to differentiate between an accepted standard of practice, an evolving standard of practice, and investigational therapies. Consequently, many insurance carriers and managed care providers have elected to cover only those indications included in FDA-approved product labeling. Coverage has frequently been denied for unlabeled or non–FDA-approved indications, citing these as "investigational" uses.[15]

The Health Insurance Association of America has created guidelines to assist insurers in assessing coverage for unlabeled drug uses. A growing number of insurance carriers are following these guidelines, which encourage the use of references such as the three authoritative drug sources, peer reviewed literature, and consultation with experts in research and clinical practice to make specific drug coverage decisions.[10]

Implications for Pharmacists

At this time, there is minimal financial impact on pharmacists when insurance coverage is denied for an unlabeled use of a medication. However, lack of FDA approval for drug reimbursement can affect patient safety. Results of a 1991 General Accounting Office survey of medical oncologists showed denials for unlabeled drug use by insurance companies were having adverse effects on the treatment decisions of one of every eight cancer patients.[16] When an oncologist learns that a service, procedure, or drug is not covered by insurance, they often choose another less effective therapy that will not jeopardize the patient's financial situation.[17] Consequently, pharmacists must consider if the chosen therapy is financially appropriate for the patient. If the patient can not afford the unlabeled medication, the pharmacist should assist in selecting the best alternative therapy.

CONCLUSION

FDA-approved product labeling is not intended to set the standard of medical practice, but to ensure consumer safety. However, product labeling often reflects the manufacturer's regulatory or financial concerns rather than current literature-supported information. Pharmacists must possess good drug information skills, and have access to accurate and unbiased information to assess therapeutic appropriateness when dispensing medications for unlabeled indications.

Pharmacists are faced with product efficacy, patient safety, liability, and reimbursement issues when medications are used for unlabeled indications. Lack of FDA approval for a specific use should not prevent a pharmacist from dispensing an available drug. Rather, drugs should be used in a manner consistent with good medical practice and in the patient's best interest. It is good pro-

fessional practice for a pharmacist to be familiar with a drug's unlabeled uses, to evaluate the literature supporting its use, and to keep the patient informed.

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Millis Commission—Study Commission on Pharmacy

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INTRODUCTION

Appointment of the Study Commission on Pharmacy culminated after a variety of conferences and studies in the 1960s and early 1970s to examine the changing role of pharmacy practice. Clinical pharmacy was emerging during the 1960s; during this period, academic pharmacy was also debating how pharmaceutical education should be changed to prepare pharmacists for the future. In 1972, American Association of Colleges of Pharmacy President Arthur E. Schwarting called for the Association to conduct an evaluation of pharmacy service within the overall structure of healthcare and an evaluation of recent and current changes in pharmacy education. His call led to the formation of the Study Commission on Pharmacy in 1992.

ORGANIZATION

To assure objectivity, Schwarting required that the Commission include other health professionals and healthcare planners in addition to pharmacists. Dr. John Millis, President of the National Fund for Medical Education, was selected to Chair the Commission. Eleven distinguished individuals from pharmacy, medicine, nursing, and the pharmaceutical industry were selected to serve on the Commission. The Commission spent two years studying the practice of pharmacy and the process of pharmacy education before publishing its report in 1975, and utilized 80 consultants to help formulate opinions, observations, and recommendations. A record of the events that led to the formation of the Commission is detailed in a historical record of the American Association of Colleges of Pharmacy.[1]

Change is most often evolutionary and not revolutionary. Reading the report of the Study Commission on Pharmacy[2] today reinforces how slow change occurs when it involves changing the purpose of a profession or the basis of an educational program to produce a professional. Reading key historical documents such as the Commission report also demonstrates that today's practice and education trends forecast the future. Many of the recommendations and opinions offered in the report of the Commission have been reiterated in subsequent reports and addresses by leaders within and outside the profession. Nevertheless, over time, many of the recommendations made by the Commission have been implemented, while other recommendations have only been partially achieved or have been discarded and not achieved at all.

The following includes a review of each of the major concepts, findings and recommendations of the Study Commission on Pharmacy; observations on the changes that have occurred since the report was published; and commentary on influence of the report on clinical pharmacy practice.

Pharmacists as Providers of Drug Information

The study commission indicated that one of the major deficiencies of the healthcare system was the lack of adequate information for those who consume, prescribe, dispense, and administer drugs. The Commission saw pharmacists as health professionals who could make an important contribution to the healthcare system of the future by providing information about drugs to consumers and health professionals.[3] The Commission judged pharmacy as a knowledge system as only being partially successful in delivering its full potential as a healthcare service. The report stimulated further emphasis on the role of pharmacists as providers of drug information. Since the report was published, tremendous progress has been made to advance the role of pharmacists as providers of drug information to patients and other health professionals. The clinical pharmacy education and practice movement emphasized the role of pharmacists as providers of drug information to patients and other health professionals. Today, organized healthcare settings clearly value and utilize pharmacists as providers of objective drug information for patients, interdisciplinary patient care, and drug use policy making. Today, a greater number of physicians in solo or group practice rely upon pharmacists for objective drug information, rather than relying solely on some texts such as the *Physician's Drug Reference*[4] or

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pharmaceutical representatives. Today's Doctor of Pharmacy curriculum prepares pharmacy graduates to retrieve, analyze, and provide drug information to other health professionals, patients, and committees concerned with health policy. In the last decade, there has been an explosion of information available to providers and patients using information technology and the Internet. It is clear that the provision of drug information, as suggested by the Commission, remains central to the future of pharmacy practice. It is also clear that our educational programs must prepare pharmacists to have more advanced drug information skills to enable them to continue to be a primary source of drug information.

Defining Pharmacy and Pharmacists

The study commission indicated that a pharmacist must be defined as an individual who is engaged in one of the steps of a system called pharmacy. The Commission asserted that they could not define a pharmacist simply as one who practices pharmacy. Rather, a pharmacist must be defined as a one who practices a part of pharmacy, which is determined by the activities carried on in the subsystems of pharmacy. Further, the Commission stated that a pharmacist is characterized by the common denominator of drug knowledge and the differentiated additional knowledge and skill required by his particular role. The Commission predicted that the future role of pharmacists would emphasize dispensing of drug information and not drugs.[5] The Commission noted that although the concept of clinical pharmacy was still evolving, it should be regarded as a powerful force internal to pharmacy that would produce change in the system of pharmacy and the practice of pharmacists.[6] The Commission opined that differentiation did not equate to specialization. The Commission defined differentiation based upon differences in place of practice, function, compensation arrangements, and patients served. The Commission stated that specialization should be based upon uniqueness of knowledge and not place or function of patient service. Further, the Commission offered cautionary comments about potential negatives in specialization and stated that specialization could only be justified by improved quality and effectiveness of patient care.[7] Although the Commission report influenced the thinking of clinical pharmacy leaders about differentiation and specialization, clinical pharmacy leaders rejected the notion that all pharmacists have the same knowledge and ability to improve the quality and effectiveness of patient care, and thus, pursued recognition of clinical pharmacy as a specialty rather than as a differentiated area of pharmacy practice as defined by the Commission. After many years, the American College of Clinical Pharmacy (ACCP) was successful in getting the Board of Pharmaceutical Specialties to recognize pharmacotherapy as a specialty practice. The terms pharmacotherapy and pharmacotherapist were used in the final specialty petition, because these terms more clearly connoted a different type of pharmacist than the terms clinical pharmacy and clinical pharmacist.[8,9] ACCP organizational leaders and individuals involved with the petition to recognize clinical pharmacy and eventually pharmacotherapy did so with a belief that patient care quality would be enhanced by board certification of pharmacists and thus meet the criterion set by the Commission. Since the report of the Commission, other knowledge-based specialties have also been approved as a part of the clinical pharmacy movement. Today, the profession continues to debate the concept of differentiation and specialization as evidenced by the current debate concerning the credentialing of pharmacists to provide disease management services to patients and the need to recognize advanced practice pharmacists in community settings who have greater knowledge and clinical skills than many community pharmacists. Thus, the observations of the Commission on differentiation and specialization live on.

Design of Pharmacy Curricula

The Commission opined that curricula of colleges of pharmacy should be based upon the competencies desired for their graduates rather than upon the basis of knowledge available in the several relevant sciences. The Commission suggested that one of the first steps to review a curriculum for a college of pharmacy would be to weigh the relative emphasis given to the physical and biological sciences against the behavioral and social sciences. The Commission said we should start with the outcomes of the curriculum and work backwards to determine the coursework needed to achieve the desired outcomes.[10] Major changes in curricula for producing pharmacists have occurred since the report of the Commission. The work of the American Association of Colleges of Pharmacy (AACP) Commission to Implement Change in Pharmaceutical Education[11,12] and the revision of standards by the American Council on Pharmaceutical Education (ACPE) led to adoption of the Doctor of Pharmacy degree as the sole entry-level degree for the profession. The clinical component of most pharmacy curricula is now the single most significant component of the curriculum. The Commission report was criticized for being too general and not specific about changes that should be made to improve the curricula of colleges of pharmacy.[2] The report of the Commission to Implement Change in Phar-

maceutical Education and revised ACPE standards provided the specific detail needed to guide colleges to revise their curricula. Regretfully, some college curricular reviews have ignored the recommendation of the Commission by approaching curriculum revision by starting with the existing curriculum and working forward to improve the outcomes of the curriculum. This approach as noted by the Commission leads to less innovative and satisfactory approaches to achieving desired curricular outcomes.

The Concept of Clinical Scientists

The Commission opined that the greatest weakness of colleges of pharmacy is a lack of an adequate number of clinical scientists who can relate their specialized scientific knowledge to the development of the practice skills required to provide effective, efficient, and needed patient services.[13] The concept of a "clinical scientist" was discussed and debated in many forums after the Commission offered this opinion. Since the report, colleges of pharmacy with a research mission have hired faculty into tenured track faculty positions that require significant clinical research for promotion in addition to teaching and service through clinical practice. These faculty are now considered clinical scientists who contribute to the advancement of scientific knowledge to enhance patient care. As tenure track clinical pharmacy faculty developed as scientists, the amount of time they spend in practice has declined due to the time demands required to be a successful researcher and teacher. In addition to tenured clinical faculty, full-time clinical track faculty positions have been developed at most colleges to teach therapeutics and other clinical courses and to serve as practitioner role models for students. Clinical pharmacy practitioners in various settings also frequently hold adjunct faculty appointments at colleges of pharmacy and serve as role models and teachers for clinical clerkships. Clinical faculty now significantly contribute to the scholarship and research conducted by colleges of pharmacy.

The Role of Graduate and Advanced Professional Educational Programs

The Commission stated that colleges of pharmacy with adequate resources should offer programs at the graduate and advanced professional level for more differentiated roles of pharmacy practice. The Commission recognized the need for advanced professional education and stated that colleges without adequate resources and outside the environment of a health science center should not consider offering advanced professional degree programs beyond the baccalaureate degree.[14] The Commission did not define the terms graduate and advanced professional level. However, the report stimulated discussion of the role of Master of Science, Ph.D., and fellowship programs as methods to develop clinical scientists, further development of Doctor of Pharmacy degree programs as advanced professional degree programs, and further development of postgraduate residency programs to produce differentiated pharmacists for advanced professional roles. The Commission considered the Doctor of Pharmacy as an advanced professional degree and warned against colleges offering this degree without adequate resources.[14] The debate on the preparation of clinical scientists or tenured track faculty continues today. A major issue likely to be confronted by academic pharmacy and the practice community is the future role of residency programs in the preparation of pharmacy graduates for general practice.

Environment for the Preparation of Pharmacists

The Commission opined that the optimal environment for pharmacy education is the university health science center but felt that adequate arrangements of colleges not located in health science centers could be made to provide an acceptable environment for the education of students at the baccalaureate level.[14] This recommendation was debated within academic pharmacy. It caused colleges of pharmacy to examine whether they had adequate resources and the environment to offer a postbaccalaureate Doctor of Pharmacy degree program. It helped spur colleges to develop relationships with hospitals and other healthcare organizations to provide clinical education and to add sufficient clinical faculty to deliver a quality postbaccalaureate Doctor of Pharmacy degree program. Over time, colleges with sufficient clinical faculty offered postbaccalaureate Doctor of Pharmacy degree programs. Soon, all colleges will offer the Doctor of Pharmacy degree as their sole professional degree program. Clinical pharmacy practice has evolved beyond the walls of the university hospital and other tertiary care hospitals to community hospital, community pharmacy, ambulatory care settings, and other innovative practice sites. Today's curricula are designed to prepare pharmacists to provide clinical pharmacy services to patients in all practice settings. All colleges now seek and have arrangements with multiple organizations to provide an acceptable environment for the preparation of pharmacists to provide clinical services.

Credentialing of Pharmacists and Pharmacy Education

The Commission opined that all aspects of credentialing of pharmacists and pharmacy education should be brought together under an umbrella organization such as a National Board of Pharmacy Examiners.[15] Over the years, this recommendation has been debated through many forums. Today, many leaders in pharmacy believe the creation of a new organization to provide oversight for all credentialing and accreditation programs in pharmacy would benefit the profession and society. A new credentialing and accreditation organization could better coordinate all programs and minimize interorganizational competition to allow a more unified vision and direction. Perhaps with time, the right political and organizational circumstances will occur to bring this recommendation of the Commission to fruition.

SUMMARY

The work of the Study Commission on Pharmacy has had an important impact on the development of clinical pharmacy and pharmaceutical education. It, coupled with other significant reports and individual and organizational leadership, have advanced the profession. As a result, pharmacists are now better educated and trained and play a more significant role in concert with other health providers to help ensure drugs are used safely and effectively in patient care.

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