

ACCP WHITE PAPER

Healthy People 2010: Challenges, Opportunities, and a Call to Action for America's Pharmacists

American College of Clinical Pharmacy

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Healthy People 2010 is an initiative sponsored by the United States Department of Health and Human Services (DHHS) that represents a detailed agenda for health promotion and disease prevention for the United States of America. Fundamentally, it is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats. Healthy People 2010 has two broad goals: to increase the quality and years of healthy life for individuals of all ages, and to decrease health disparities among different regions of the country and segments of the population.

Healthy People 2010 consists of 467 specific health objectives in 28 primary focus areas (e.g., respiratory diseases, diabetes mellitus, cancer) to be achieved by the end of the first decade of the new century. Each of the 28 focus areas (Table 1) has a single goal that identifies the overall purpose of the focus area and serves as the basis on which the specific objectives are framed. Many of the objectives have specific targets that are numerically set, tracked, and evaluated by using data from major national health sources.

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Twenty-one such objectives from 12 of the 28 focus areas were designated as Leading Health Indicators by DHHS for the purpose of monitoring the progress of the nation in achieving the Healthy People 2010 objectives. These indicators include areas of major health priorities and will serve to provide ongoing snapshots of the overall health of the Nation.

Founded on earlier federal initiatives—namely, the 1979 Surgeon General's Report, *Healthy People*, and *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*—the Healthy People 2010 program establishes comprehensive national health objectives, serves as a national road map for public health, and provides a basis for the development of other state and community health-related plans. The focus areas and objectives of Healthy People 2010 were developed by various federal health and public service agencies, with input from The Healthy People Consortium—an alliance of more than 350 national organizations (including the American College of Clinical Pharmacy [ACCP]) and 250 state public health, mental health, substance abuse, and environmental agencies.

Detailed information about Healthy People 2010 and specific focus areas and objectives can be found at <http://www.healthypeople.gov/>. These materials may be reproduced and disseminated freely as part of local, regional, or national campaigns to improve public health. According to DHHS, this information is intended to assist states, communities, professional

Table 1. Healthy People 2010 Focus Areas by Category

Category	Perceived Role of Pharmacists in Meeting Objectives	Focus Areas
1	Pharmacists' role is well established. Leadership role is well documented in the literature and/or positive outcomes data are available. Pharmacists are active in these areas, receive adequate education or specialized training, and have adequate manpower.	Diabetes mellitus Heart disease and stroke Immunization and infectious diseases ^a Medical product safety Respiratory diseases
2	Pharmacists are active in these areas but have not yet established a leadership role. A leadership role is possible or may be emerging. Pharmacists are capable and reasonably well positioned to assume a leadership role. Currently, documentation of pharmacy's role is insufficient and/or outcomes data are limited.	Access to quality health services ^a Arthritis, osteoporosis, and chronic back conditions Cancer Chronic kidney disease Family planning Health communication Human immunodeficiency virus ^a Tobacco use ^a Mental health and mental disorders ^a
3	Opportunities exist for pharmacists' involvement but primarily in a supportive role. Future leadership role is possible, but only if additional efforts are made and if existing barriers (e.g., inadequate training, insufficient manpower) are addressed.	Disability and secondary conditions Educational and community-based programs Maternal, infant, and child health ^a Nutrition and overweight ^a Physical activity and fitness ^a Sexually transmitted diseases ^a Substance abuse ^a
4	Little or no role exists for pharmacists in these areas, and opportunities for expansion are limited.	Environmental health ^a Food safety Injury and violence prevention ^a Occupational safety and health Oral health Public health infrastructure Vision and hearing

^aFocus areas with objectives designated as Leading Health Indicators.

organizations, and others to develop programs aimed at improving public health. The DHHS specifically encourages individuals, groups, and organizations to integrate Healthy People 2010 objectives into current programs, special events, publications, and meetings. Health care providers are encouraged to promote healthier lifestyles for their patients. Businesses are encouraged to use Healthy People 2010 objectives as the basis for worksite health promotion activities and community-based initiatives. Other groups, including schools, universities, and civic and faith-based organizations, also are urged to develop initiatives to improve the health of their communities.

Pharmacists have been counted among the most trusted professionals in the United States and are the most widely accessible health care providers for nearly all segments of the population. As their education and training have advanced, pharmacists have assumed greater and ever more meaningful patient-care responsibilities. The scope of pharmacy practice continues to

evolve into a positive and promising patient-focused model. The expanding role of the pharmacist has drawn the interest and attention of physicians and other groups. A recent statement by the American College of Physicians–American Society of Internal Medicine explored the increased scope of practice of pharmacists in the United States.¹

Pharmacists' roles in patient care and their overall contributions to health care are becoming more widely recognized by other health care professionals, health policy decision makers, and the general public. Pharmacists have contributed notably to patient care and public health. The impact of clinical pharmacy services has been well documented in the inpatient setting, and to a lesser extent in the ambulatory and community settings.^{2,3} The value and acceptance of clinical pharmacy services were first documented in the 1970s and 1980s. Since that time, pharmacists' services and involvement in patient care have been associated with improved health and economic outcomes,⁴⁻⁷ reduced adverse drug

events,⁸ improved quality of life,⁹ and reduced morbidity and mortality.^{10–12} These accomplishments have been achieved through gradual expansion of traditional roles and, in some cases, through the emergence of collaborative drug therapy management programs.¹³ Nonetheless, the potential for pharmacists to effect dramatic improvements in American public health remains largely untapped.

Because drugs are so important in the prevention and treatment of many conditions, and because of the distinctive education, training, and positioning of pharmacists in their communities, pharmacy has the potential to play a critical role in improving public health and bringing needed knowledge, resources, and expertise to those on the fringes of the United States health care system. This can be achieved by pharmacists acting individually in their own communities or through coordinated efforts along with national, state, and local organizations; professional associations; and schools of pharmacy. Such efforts should be geared to closing the gaps in health care, improving public health, and reducing disparities in access to health services. This report examines the challenges facing pharmacists and the boundless opportunities available to them to assume leading roles in the national effort to achieve the goals and objectives of Healthy People 2010. In some cases, this may involve expansion of existing roles, whereas in other cases it may require that pharmacists adopt new roles that heretofore were considered beyond the scope of traditional pharmacy practice.

Purpose

The 2001–2002 ACCP Public and Professional Affairs Committee was asked to review the Healthy People 2010 objectives and prepare an analysis that at a minimum would do the following:

- Identify those objectives for which pharmacists are especially capable or positioned to exert a significant leadership role in conceiving and/or implementing programs designed to meet the stated objective.
- Identify those objectives to which pharmacists would be expected to contribute but would not necessarily be expected to take a leadership role in conceiving and/or implementing programs designed to meet the stated objective.
- For those objectives identified above, recognize

gaps to assess how well the profession is doing in contributing to the objective's achievement or in fulfilling its leadership role.

- Offer recommendations to the profession as a whole and to ACCP in particular intended to narrow any gaps identified.

The primary objectives of this White Paper are to describe the pharmacy implications of Healthy People 2010, identify the major challenges and opportunities provided by this national initiative, and serve as a call for mobilizing pharmacists in the United States to help achieve the stated goals and objectives of Healthy People 2010.

Methods

To facilitate its work, the Committee classified each of the 28 Healthy People 2010 primary focus areas into one of four categories according to the perceived role of pharmacists in meeting the specified objectives (Table 1). Subsequently, a gaps analysis was conducted for each of the 14 focus areas that the Committee had placed into either category 1 or 2 (i.e., those for which a pharmacy role is already well established or for which pharmacists are capable and reasonably well positioned to assume a leadership role). At a minimum, these analyses included conducting a comprehensive literature review to identify pharmacists' contributions toward each of the focus areas, and surveying individuals and/or organizations knowledgeable about the specific focus area to identify gaps and determine opportunities for pharmacists.

Literature Review

The articles and studies cited in this White Paper were identified largely through the use of multiple, electronic scientific and medical bibliographic databases. These included MEDLINE, EMBASE, and International Pharmaceutical Abstracts. Other supplemental databases, such as the Cochrane Library, Current Contents, and Web of Science, were used for several of the focus areas. In addition, the reference lists of published reviews and articles were scanned for relevant literature. Also, experts on the topics were contacted to identify landmark articles and other relevant references. Unfortunately, the breadth of this White Paper does not allow for a systematic review of all published articles pertaining to each of the focus areas. An exhaustive review regarding pharmacists' general contributions to health care is beyond the scope of this report. This White

Paper is not intended to serve as a complete bibliography of pharmacy activities pertaining to each of the focus areas. In some cases in which data were limited and full published reports were unavailable, the authors chose to cite published abstracts.

This White Paper generally addresses the specific Healthy People 2010 objectives as they were written for each focus area—not necessarily as we would have liked them to be. In some cases, the objectives, as they pertain to pharmacy, are not ideal. Although pharmacy groups were asked to give their input regarding the final Healthy People 2010 document, pharmacists apparently were not directly involved in the working groups that developed the specific objectives for the focus areas. It is hoped that pharmacists will be fully represented on working panels of future Healthy People initiatives.

Focus Area–Specific Gaps Analyses

A gaps analysis is provided for each of the 14 focus areas that were classified as category 1 or category 2. All of the analyses used the following format:

- **Background:** Background on the focus area is provided, with emphasis on why it is important. Why is it in the public's interest that pharmacists play an active role in this area?
- **Pharmacy's position:** How is the pharmacy profession positioned to help achieve the specific objectives of this focus area?
- **Documented impact:** What have pharmacists already accomplished in this focus area (statements supported by primary literature)?
- **Future directions:** What must pharmacists do to contribute further and have a meaningful impact toward achieving the specific objectives of this focus area?
- **Challenges and opportunities:** What are the major challenges and opportunities as they pertain to this focus area?
- **Recommendations:** What recommendations (especially as they pertain to challenges and opportunities) can be offered to ACCP and to the pharmacy profession to further pharmacists' roles in meeting the specific objectives for this focus area?

Access to Quality Health Services

The overall goal for this focus area is to improve access to comprehensive, high-quality health care services.

Background

Improvement in access to first-rate health care services is essential for increasing the years of healthy life and enhancing quality of life for all persons in the United States. Central to this vision is that these improvements should be manifest for all individuals, regardless of ethnic, cultural, or socioeconomic differences. A 2002 report from the Institute of Medicine documented that racial and ethnic minorities continue to receive a lower quality of health care than that of other groups.¹⁴ Among the many causes for unequal treatment were stereotyping; the effect of cost-containment measures; and barriers of language, geography, and culture. Interestingly, of the nine areas identified for research to improve these disparities, one was to understand the role of nonphysician health care professionals, including pharmacists, in contributing to health care disparities. It is hoped that this sobering Institute of Medicine report, in addition to the imperatives outlined by Healthy People 2010, will encourage efforts of pharmacists to reduce these disparities.

Objectives in this section of Healthy People 2010 include those related to clinical preventive care, primary care, emergency services, and long-term care and rehabilitative services. Participation of pharmacists is necessary to meet several of these objectives. Increasing costs and fragmentation of the health care system are well recognized, with consumers facing difficulties obtaining care in a timely fashion and then, often, from a practitioner with whom they are not familiar.

Clinical pharmacists already play an important role in primary care, and community pharmacists, who often know their patients very well, can intervene to refer the patient to another health care provider or otherwise provide interim advice. In addition, some patients, especially those with multiple medical problems, may depend on individualized care from the pharmacist to avoid problems with drugs. Finally, there are individuals, particularly from underserved populations, who do not have a source of ongoing primary care or who are unable to pay for drugs. Medical indigency has been determined to be related directly to nonadherence to therapy.¹⁵ In such cases, the pharmacist may be able to direct the person to appropriate sources of care or to find help in paying for drugs. For all these reasons, it is in the public's interest that pharmacists play an active role in improving access to care.

Pharmacy's Position

Clinical Preventive Care

As one of the most accessible health care professionals, community pharmacists have distinct opportunities to direct patients to appropriate care. Pharmacists are well situated to offer some aspects of preventive care, in particular those related to counseling about health behaviors (objective 1-3, Table 2). Many patients receiving drugs for either acute or chronic illnesses need counseling regarding preventive and lifestyle strategies as much as they do about their drug therapy. Counseling about diet, exercise, or smoking cessation are important complements to drug management for cardiovascular risk, for example.

A special advantage of the community pharmacist is the opportunity to reinforce lifestyle changes at frequent intervals. Curricula in pharmacy schools emphasize a comprehensive approach to pharmacotherapy that includes disease etiology, risk factors, diagnosis, and drug and nondrug modalities for prevention and treatment. Increasingly, community pharmacies also are offering clients a variety of health screenings and other preventive services.

Pharmacists are interested in incorporating preventive care into their practices. Surveyed pharmacists indicated that alcohol and tobacco were clearly recognized as important causes of morbidity and mortality, and that as pharmacists they should play a role in health promotion and disease prevention.¹⁶ Other community pharmacists overwhelmingly (90%) indicated that they were interested in incorporating preventive strategies into their practice settings.¹⁷ Other work has shown that pharmacists are willing to play a role in programs aimed at providing sterile syringes to patients to prevent the spread of infectious diseases among those who take intravenous drug.¹⁸ Finally, financial, language, and other barriers facing underserved groups, such as Vietnamese immigrants, have been identified and strategies proposed to overcome these barriers.¹⁹

One reason that pharmacists are well positioned to contribute to preventive care is that provision of such care is considered basic to the values of the profession: "Pharmaceutical care is the responsible provision of drug therapy to achieve definite outcomes that improve a patient's quality of life. These outcomes include: cure a disease, eliminate or reduce symptoms, arrest or slow a disease process, and prevent a disease."²⁰

Primary Care

With the existing number of pharmacies, their presence in communities of almost any size and location, their extended hours, and the walk-in character of the community pharmacy, the pharmacist is the most accessible of health care professionals.²¹⁻²³ Community pharmacists generally are not categorized as primary care providers, but their accessibility and familiarity with their patients may make them the first health care professional sought when a problem arises. The pharmacist can provide a triage function. Interestingly, the importance of factors such as evening and weekend availability, in reference to physicians' office hours, was stressed in Healthy People 2010, although only a minority provided such coverage.

Pharmacists working within hospital or clinic settings already provide many important aspects of primary care, including management of a variety of disease states. For objective 1-9 (Table 2) in particular, pharmacists are extremely well positioned to help reduce hospitalization for three specified ambulatory care-sensitive conditions: childhood asthma, adult diabetes mellitus, and immunization-preventable influenza and pneumonia. Emphasis on treatment and monitoring of those with asthma and diabetes in pharmacy education and a focus on pharmaceutical care of those individuals by pharmacists in clinics and community settings provide a strong background for the profession in this regard.

Emergency Services

Healthy People 2010 objectives related to these topics are very tightly defined and not explicitly relevant to pharmacist involvement (objectives 1-10 through 1-13, Table 2). However, the narrative noted that many individuals, especially the underserved, now rely on emergency department care for their primary care needs, including immunizations. Pharmacists working in emergency departments thus could provide this service, as well as other services that relate to primary care or that prevent further emergency department admissions.

Long-term Care and Rehabilitative Services

The objectives for this topic are limited to increasing the proportion of persons with access to long-term care and reducing the frequency of pressure ulcers. For these objectives, pharmacy has a limited role. However, long-term care

Table 2. Objective Numbers and Short Titles for Healthy People 2010 Objectives for Category 1 and 2 Focus Areas Identified in Table 1

Objective Number by Focus Area	Short Title of Objective
Access to quality health care	
Clinical preventive care	
1-1	Persons with health insurance
1-2	Health insurance coverage for clinical preventive services
1-3	Counseling about health behaviors
Primary care	
1-4	Source of ongoing care
1-5	Usual primary care provider
1-6	Difficulties or delays in obtaining needed health care
1-7	Core competencies in health provider training
1-8	Racial and ethnic representation in health professions
1-9	Hospitalization for ambulatory-care-sensitive conditions
Emergency services	
1-10	Delay or difficulty in getting emergency care
1-11	Rapid prehospital emergency care
1-12	Single toll-free number for poison control centers
1-13	Trauma care systems
1-14	Special needs of children
Long-term care and rehabilitative services	
1-15	Long-term care services
1-16	Pressure ulcers among nursing home residents
Arthritis, osteoporosis, and chronic back conditions	
Arthritis and other rheumatic conditions	
2-1	Mean number of days without severe pain
2-2	Activity limitations due to arthritis
2-3	Personal care limitations
2-4	Help in coping
2-5	Employment rate
2-6	Racial differences in total knee replacement
2-7	Seeing a health care provider
2-8	Arthritis education
Osteoporosis	
2-9	Cases of osteoporosis
2-10	Hospitalization for vertebral fractures
Chronic back conditions	
2-11	Activity limitations due to chronic back conditions
Cancer	
3-1	Overall cancer deaths
3-2	Lung cancer deaths
3-3	Breast cancer deaths
3-4	Cervical cancer deaths
3-5	Colorectal cancer deaths
3-6	Oropharyngeal cancer deaths
3-7	Prostate cancer deaths
3-8	Melanoma deaths
3-9	Sun exposure and skin cancer
3-10	Provider counseling about cancer prevention
3-11	Papanicolaou (Pap) tests
3-12	Colorectal cancer screening
3-13	Mammograms
3-14	Statewide cancer registries
3-15	Cancer survival

pharmacists play an extremely valuable pharmaceutical care role, advising prescribers and nurses, monitoring therapy for efficacy and toxicity, and preventing adverse drug events.

Documented Impact

Other sections of this report provide a more complete summary of the pharmacist's role in the

Table 2. Objective Numbers and Short Titles for Healthy People 2010 Objectives for Category 1 and 2 Focus Areas Identified in Table 1 (continued)

Objective Numbers by Focus Area	Short Title of Objective
Chronic kidney disease	
4-1	End-stage renal disease
4-2	Cardiovascular disease deaths in persons with chronic kidney failure
4-3	Counseling for chronic kidney failure care
4-4	Use of arteriovenous fistulas
4-5	Registration for kidney transplantation
4-6	Waiting time for kidney transplantation
4-7	Kidney failure due to diabetes
4-8	Medical therapy for persons with diabetes and proteinuria
Diabetes mellitus	
5-1	Diabetes education
5-2	New cases of diabetes
5-3	Overall cases of diagnosed diabetes
5-4	Diagnosis of diabetes
5-5	Diabetes deaths
5-6	Diabetes-related deaths
5-7	Cardiovascular disease deaths in persons with diabetes
5-8	Gestational diabetes
5-9	Foot ulcers
5-10	Lower extremity amputations
5-11	Annual urinary microalbumin measurement
5-12	Annual glycosylated hemoglobin measurement
5-13	Annual dilated eye examinations
5-14	Annual foot examinations
5-15	Annual dental examinations
5-16	Aspirin therapy
5-17	Self-monitoring of blood glucose level
Family planning	
9-1	Intended pregnancy
9-2	Birth spacing
9-3	Contraceptive use
9-4	Contraceptive failure
9-5	Emergency contraception
9-6	Male involvement in pregnancy prevention
9-7	Adolescent pregnancy
9-8	Abstinence before age 15 years
9-9	Abstinence among adolescents aged 15–17 years
9-10	Pregnancy prevention and STD protection
9-11	Pregnancy prevention education
9-12	Problems in becoming pregnant and maintaining a pregnancy
9-13	Insurance coverage for contraceptive supplies and services
Health communication	
11-1	Households with Internet access
11-2	Health literacy
11-3	Research and evaluation of communication programs
11-4	Quality of Internet health information sources
11-5	Centers for excellence
11-6	Satisfaction with health care providers' communication skills
Heart disease and stroke	
Heart disease	
12-1	Coronary heart disease deaths
12-2	Knowledge of symptoms of heart attack and importance of calling 911
12-3	Artery-opening therapy
12-4	Bystander response to cardiac arrest
12-5	Out-of-hospital emergency care
12-6	Heart failure hospitalizations
Stroke	
12-7	Stroke deaths
12-8	Knowledge of early warning symptoms of stroke

Table 2. Objective Numbers and Short Titles for Healthy People 2010 Objectives for Category 1 and 2 Focus Areas Identified in Table 1 (continued)

Objective Numbers by Focus Area	Short Title of Objective
Heart disease and stroke (continued)	
Blood pressure	
12-9	High blood pressure
12-10	High blood pressure control
12-11	Action to help control blood pressure
12-12	Blood pressure monitoring
Cholesterol	
12-13	Mean total blood cholesterol levels
12-14	High blood cholesterol levels
12-15	Blood cholesterol screening
12-16	Low-density lipoprotein cholesterol level in patients with coronary heart disease
HIV	
13-1	New AIDS cases
13-2	AIDS among men who have sex with men
13-3	AIDS among persons who inject drugs
13-4	AIDS among men who have sex with men and who inject drugs
13-5	New HIV cases
13-6	Condom use
13-7	Knowledge of serostatus
13-8	HIV counseling and education for persons in substance-abuse treatment
13-9	HIV/AIDS, STD, and TB education in state prisons
13-10	HIV counseling and testing in state prisons
13-11	HIV testing in patients with TB
13-12	Screening for STDs and immunization for hepatitis B
13-13	Treatment according to guidelines
13-14	HIV-infection deaths
13-15	Interval between HIV infection and AIDS diagnosis
13-16	Interval between AIDS diagnosis and death from AIDS
13-17	Perinatally acquired HIV infection
Immunization and infectious diseases	
Diseases preventable through universal vaccination	
14-1	Vaccine-preventable diseases
14-2	Hepatitis B in infants and young children
14-3	Hepatitis B in adults and high-risk groups
14-4	Bacterial meningitis in young children
14-5	Invasive pneumococcal infections
Diseases preventable through targeted vaccination	
14-6	Hepatitis A
14-7	Meningococcal disease
14-8	Lyme disease
Infectious diseases and emerging antimicrobial resistance	
14-9	Hepatitis C
14-10	Identification of persons with chronic hepatitis C
14-11	TB
14-12	Curative therapy for TB
14-13	Treatment for high-risk persons with latent TB infection
14-14	Timely laboratory confirmation of TB cases
14-15	Prevention services for international travelers
14-16	Invasive early-onset group B streptococcal disease
14-17	Peptic ulcer hospitalizations
14-18	Antibiotics prescribed for ear infections
14-19	Antibiotics prescribed for common cold
14-20	Hospital-acquired infections
14-21	Antimicrobial use in intensive care units

Table 2. Objective Numbers and Short Titles for Healthy People 2010 Objectives for Category 1 and 2 Focus Areas Identified in Table 1 (continued)

Objective Numbers by Focus Area	Short Title of Objective
Immunization and infectious diseases (continued)	
Vaccination coverage and strategies	
14-22	Universally recommended vaccination of children aged 19–35 months
14-23	Vaccination coverage for children in day care, kindergarten, and first grade
14-24	Fully immunized young children and adolescents
14-25	Providers who measure childhood vaccination coverage levels
14-26	Children participating in population-based immunization registries
14-27	Vaccination coverage among adolescents
14-28	Hepatitis B vaccination among high-risk groups
14-29	Influenza and pneumococcal vaccination of high-risk adults
Vaccine safety	
14-30	Adverse events from vaccinations
14-31	Active surveillance for vaccine safety
Medical product safety	
17-1	Monitoring of adverse medical events
17-2	Linked, automated information systems
17-3	Provider review of drugs taken by patients
17-4	Receipt of useful information about prescriptions from pharmacies
17-5	Receipt of oral counseling about drugs from prescribers and dispensers
17-6	Blood donations
Mental health and mental disorders	
Mental health status improvement	
18-1	Suicide
18-2	Adolescent suicide attempts
18-3	Serious mental illness among homeless adults
18-4	Employment of persons with a serious mental illness
18-5	Eating disorder relapses
Treatment expansion	
18-6	Primary care screening and assessment
18-7	Treatment for children with mental health problems
18-8	Juvenile justice facility screening
18-9	Treatment for adults with mental disorders
18-10	Treatment for co-occurring disorders
18-11	Adult jail-diversion programs
State activities	
18-12	State tracking of consumer satisfaction
18-13	State plans addressing cultural competence
18-14	State plans addressing elderly persons
Respiratory diseases	
Asthma	
24-1	Deaths from asthma
24-2	Hospitalizations for asthma
24-3	Hospital emergency department visits for asthma
24-4	Activity limitations
24-5	School or work days lost
24-6	Patient education
24-7	Appropriate asthma care
24-8	Surveillance systems
COPD	
24-9	Activity limitations due to chronic lung and breathing problems
24-10	Deaths from COPD
Obstructive sleep apnea	
24-11	Medical evaluation and follow-up
24-12	Vehicular crashes related to excessive sleepiness

Table 2. Objective Numbers and Short Titles for Healthy People 2010 Objectives for Category 1 and 2 Focus Areas Identified in Table 1 (continued)

Objective Numbers by Focus Area	Short Title of Objective
Tobacco use	
In population groups	
27-1	Adult tobacco use
27-2	Adolescent tobacco use
27-3	Initiation of tobacco use
27-4	Age at first tobacco use
Cessation and treatment	
27-5	Smoking cessation by adults
27-6	Smoking cessation during pregnancy
27-7	Smoking cessation by adolescents
27-8	Insurance coverage of cessation treatment
Exposure to secondhand smoke	
27-9	Exposure to tobacco smoke at home among children
27-10	Exposure to environmental tobacco smoke
27-11	Smoke-free and tobacco-free schools
27-12	Worksite smoking policies
27-13	Smoke-free indoor air laws
Social and environmental changes	
27-14	Enforcement of illegal tobacco sales to minors laws
27-15	Retail license suspension for sales to minors
27-16	Tobacco advertising and promotion targeting adolescents and young adults
27-17	Adolescent disapproval of smoking
27-18	Tobacco control programs
27-19	Preemptive tobacco control laws
27-20	Tobacco product regulation
27-21	Tobacco tax

STD = sexually transmitted disease; HIV = human immunodeficiency virus; AIDS = acquired immunodeficiency syndrome; TB = tuberculosis; COPD = chronic obstructive pulmonary disease.

care of patients with various health problems. The value and acceptance of pharmaceutical services provided by pharmacists in ambulatory care settings have been described.²⁴ A sample of other recent work is described in this report to establish the point that pharmacists already provide many important aspects of primary care or preventive care.

Clinical Preventive Care

Many pharmacists have been trained in immunization and provide this service to patients.^{25, 26} A further preventive care intervention is afforded by pharmacist-led smoking-cessation programs.²⁷ In another type of intervention, a telephone-based drug information service provided to health care providers and consumers yielded positive patient outcomes in a significant proportion of calls (either disease or symptom prevention, or symptom relief).²⁸ Pharmacist intervention in disease prevention less commonly associated with drug therapy also has been studied. For example, counseling in skin cancer prevention by pharmacists was enhanced, based

on client surveys, after pharmacists were provided training on the topic.²⁹ Another opportunity is offered when adolescents obtain emergency contraceptive pills directly from pharmacists. In one such study, teenagers sought out pharmacists because of accessibility and privacy and were satisfied with the service. Most did need further follow-up for improved birth control methods or screening for sexually transmitted diseases, demonstrating a potential role for pharmacists to provide further counseling and referral.³⁰ Pharmacist counseling with regard to drug therapy adherence and other health behaviors is well documented, including those carried out with underserved or indigent populations. As financial barriers can jeopardize adherence with transplant drug therapies, pharmacists' effect on the use of these drugs was examined, with pharmacists successfully increasing adherence rates.³¹ Studies of osteoporosis screening in community pharmacies have indicated client satisfaction, willingness to pay for the service, and favorable response of prescribers.^{32, 33}

Primary Care

Numerous programs have demonstrated that pharmacist interventions are effective in the management of a variety of disease states, including adult and pediatric asthma. For example, a pharmacist-led, comprehensive asthma management program was successful in reducing the number of emergency department visits for acute exacerbations of asthma.³⁴ Also, pharmacists have played an important role in landmark studies that have had a major effect on asthma care in general, as well as a leadership role in projects to identify inner-city children at high risk of asthma.^{35, 36} In the area of diabetes, numerous pharmacist-led programs have been shown to yield better glycemic control and fewer health care visits.³⁷⁻³⁹ Implementation and prospective evaluation of pharmacist services for patients with hyperlipidemias have been carried out in a variety of settings and in collaborative practices with physicians and patients. Numerous studies in settings such as Veterans Affairs clinics, community pharmacies, and indigent programs have shown that pharmacists can increase patient adherence to therapy, achieve reductions in total and low-density lipoprotein cholesterol levels, and increase the proportion of patients achieving recognized treatment goals with increased patient satisfaction and at minimal cost.⁴⁰⁻⁴⁶ The importance of clinical pharmacists in the care of patients with heart failure has been described recently.⁴⁷

Pharmacists also have been successful in providing health care and drug assistance to underserved individuals, often using manufacturer-sponsored drug assistance programs.⁴⁸ In one example, pharmacist volunteers worked in the drug program of a countywide health care program for homeless persons. Donations for the program totaled \$194,000 by the fourth year of the program, with costs of only \$300/month at that point.⁴⁹ In another drug assistance program run by a pharmacist and social worker, a net savings of \$127,000 resulted, with experienced staff using the full spectrum of resources for indigent patients. In this program, 13% of savings was derived from pharmaceutical companies and 63% was from Medicaid.⁵⁰

Such efforts by pharmacists are crucial. Although pharmacists are physically accessible to most individuals, inability of many patients to pay for expensive drugs reduces the benefit of this accessibility. Pharmacoeconomic modeling has been used to promote a role for clinical

pharmacists in a number of important disease states (e.g., angiotensin-converting enzyme inhibitors for diabetic patients with proteinuria or in patients with asymptomatic left ventricular dysfunction; use of β -blockers after myocardial infarction).⁵¹ An initiative to provide patients with financial or pharmaceutical company assistance programs was developed in an interdisciplinary hypertension clinic. Of those patients with uncontrolled hypertension at the start of the program and who were followed up for 6 months, 71% had a 10-mm Hg improvement in systolic blood pressure.⁵² This same group also has created partnerships with community groups and a variety of health care providers to establish cardiovascular educational programs for individuals with specific risk factors. This program, and the others mentioned above, provide compelling evidence that pharmacists play significant roles in ensuring access to high-quality pharmaceutical care, with careful attention to cost issues, for a wide spectrum of patients with a variety of diseases.

Future Directions

In embracing their expanded clinical role, pharmacists need to develop their practices to include the concepts of preventive care routinely. Pharmacists need to continue to enhance their role as providers not just of drug products, but also of services that ensure optimal drug use and prevent medication errors.

Pharmacists need to increase documentation of their innovative efforts in pharmaceutical care, particularly as related to improvement of care for underserved populations. Such documentation can help other pharmacy practitioners succeed in similar efforts in their own settings.

Pharmacists need to work with their colleagues in different practice settings, and with other health professionals, to develop strategies to care for individuals most in need, such as those facing especially high health care risks or those who have the most difficulty accessing care. Partnerships with other health care professionals and with community groups are likely to provide better care than can be offered by any one group, and pharmacists are likely to derive a variety of benefits and increased professional satisfaction from participation in such partnerships.

Challenges and Opportunities

Maintaining quality in the essential arenas of pharmaceutical care is one challenge. It is crucial

that, while broadening the scope of pharmacists' roles, practitioners do not lose sight of the basic elements of drug counseling. For example, a survey of patients with asthma indicated that counseling about asthma drugs in community pharmacies was inadequate and did not sufficiently address either the educational needs of patients or the recommendations of the National Asthma Education and Prevention Program.⁵³

Pharmacists will continue to be pressed for time and energy while they struggle to create new modalities for providing pharmaceutical care. It is important that pharmacists learn from each other's efforts to obtain payment for their interventions. Compensation for clinical preventive services is especially difficult and will likely require allegiances with public health departments or public health initiatives.

Documentation of pharmacists' innovative efforts to provide pharmaceutical care, and to prove the benefits and cost-effectiveness of interventions, will be necessary to consolidate and strengthen the patient care role of the profession. However, recent regulations from the Health Insurance Portability and Accountability Act (HIPAA) have the potential to restrict the ability of practitioners to disseminate their findings.^{54, 55}

A continuing challenge of major importance in reducing disparities in health care, for pharmacy as well as medicine, has been the inability of the professions to train a sufficient number of ethnic minority practitioners. In 1995–1996, for example, underrepresented minorities (African-American, Hispanic, and American Indian) received only 9.4% of the baccalaureate pharmacy degrees and 13.4% of the entry-level doctor of pharmacy degrees. In 2000–2001, these numbers were 9.5% and 10.3%, respectively. As noted in Healthy People 2010, minority health professionals are more likely to serve in areas with higher numbers of underrepresented ethnic minorities. It is thus crucially important that schools of pharmacy recruit and graduate a higher number of such individuals. One strategy to aid this mission is to increase awareness within ethnic communities of pharmacy as a desirable and achievable professional goal.

Recommendations

- The ACCP should continue its efforts to participate in, and to have pharmacists fully contribute to, the work of national health

policy-making bodies. Such participation will be enhanced by pharmacists who are fluent in the "language" of public health policy.

- Schools of pharmacy should continue to intensify their efforts to recruit and graduate individuals from underrepresented minorities.
- Schools of pharmacy should seek to enhance the focus on preventive health care strategies in their pharmacotherapy curricula and experiential programs.
- The ACCP should encourage collaboration among practitioners and between practitioners and academic pharmacists to publish in peer-reviewed journals studies that evaluate the benefits of pharmacy services.

Arthritis, Osteoporosis, and Chronic Back Conditions

The overall goal for this focus area is to prevent illness and disability related to arthritis and other rheumatic conditions, osteoporosis, and chronic back conditions.

Background

There are 11 specific objectives related to this goal that are grouped into three domains: arthritis and other rheumatic conditions, osteoporosis, and chronic back conditions (Table 2).

Pharmacy's Position

The rich opportunity for pharmacist-patient communication creates a favorable environment for patient education. The main goal of Healthy People 2010 with respect to arthritis, osteoporosis, and chronic back pain is to prevent illness and disability. This goal may be best approached through prevention, patient education, and disease management interventions. The most common pharmacy practice models today may not be designed to handle this task efficiently. However, specific objectives of Healthy People 2010 focus on providing disease education, limiting days of severe pain, and minimizing activity limitation. These issues can be readily addressed during disease and drug counseling sessions provided by pharmacists.

Documented Impact

Arthritis and Back Pain

The cost-effectiveness of health care professionals providing disease management

services to patients with osteoarthritis of the knee has been evaluated.⁵⁶ The use and cost of ambulatory medical services were compared in 211 patients assigned to either a control or intervention group that received individualized instruction and follow-up emphasizing nonpharmacologic management of joint pain. The self-care intervention group was associated with a lower mean number of clinic visits/patient and lower clinic costs compared with those of the control group. No difference was noted between groups with respect to use and costs of outpatient pharmacy, laboratory, or radiology services during the 1-year study period. The cost to deliver self-care intervention was estimated to be \$58.70/patient, and the savings associated with fewer primary care visits exceeded the cost of self-care education for greater than 50% of patients in the intervention group.

The ability of pharmacists to positively influence the prescribing of nonsteroidal antiinflammatory drugs (NSAIDs) or other drugs for patients with musculoskeletal disorders has been demonstrated through different approaches.^{57, 58} In one report, the authors described the effect of pharmacist intervention in patients with chronic pain.⁵⁷ Ninety-six patients with rheumatoid arthritis, or who regularly took NSAIDs or combination analgesics, were interviewed by a pharmacist after their medical records were reviewed. Issues addressed included lack of pain relief, lack of understanding of pain management, potential drug interactions, and potential adverse effects. Using validated pain evaluation scales, pharmacists were able to identify patients with poor outcomes from current therapy and refer them to their primary physician. Pharmacist interviews also identified patients requiring advice to optimize therapy or who needed referral to address potential inappropriate therapy. The authors also concluded that evidence of adequate monitoring in patients taking NSAIDs and disease-modifying antirheumatic drugs was poor.

A group of Australian researchers evaluated the effect of academic detailing by pharmacists to general, community-based physicians regarding the appropriate prescribing of NSAIDs.⁵⁸ The intervention involved the distribution of educational materials to each physician in a particular geographic area followed by a personal visit and discussion with a pharmacist. Prescribing patterns in another geographic area served as a control. Academic detailing was well received by general practitioners in this cohort,

and mean daily doses of NSAIDs relative to other analgesics were significantly reduced relative to the control area.

Other researchers evaluated the potential for pharmacists to use point-of-service health status assessment surveys like the Short Form-36 to identify and resolve drug-related problems in ambulatory patients with a self-reported diagnosis of osteoarthritis, rheumatoid arthritis, or low back pain.⁵⁹ This 12-month, prospective, noncontrolled evaluation involved patients using touch-screen computers at quarterly pharmacy visits to report their health status and answer questions about limitations associated with their musculoskeletal condition. Pharmacists then used this information while interviewing patients to assess for drug-related problems. During the 1-year study period, 388 (84%) of 461 patients returned for their 12-month pharmacy visit, and 926 drug-related problems were identified. Patients with no drug-related problems had significantly higher physical component summary scores on the Short Form-36 at baseline, 6 months, and 12 months. At 12 months, actions performed by pharmacists resulted in resolution or improvement of drug-related problems in 71% of cases. These findings suggest that drug-related problems are prevalent in ambulatory patients with osteoarthritis, rheumatoid arthritis, or low back pain, and that community pharmacists can identify patients at risk for these problems and take actions to resolve them.

Osteoporosis

Disease management activities by pharmacists that focused on prevention and treatment of osteoporosis have been reported.⁶⁰⁻⁶³ In a model in which pharmacists or nurses measured calcaneal bone density, the authors administered a questionnaire to determine osteoporosis risk factors and provided National Osteoporosis Foundation literature to women aged 65 years or older.⁶⁰ With patient consent, bone mass and risk factor data along with the National Osteoporosis Foundation literature were given to primary care providers.

Another model of pharmacist-coordinated osteoporosis disease management activities in an integrated health care system has been described.⁶¹ The Community Pharmacist Osteoporosis Education Program was a pilot project designed to improve bone health behavior and included physician and allied health care

provider guidelines, community intervention, bone density testing, and outcomes analysis. Participating pharmacists were given comprehensive training and subsequently held classes for interested members in the community. Patient information was collected through baseline and follow-up questionnaires. High-risk individuals received a follow-up telephone contact. Primary care physicians were notified about the program and their patients' participation. The classes were well received by all of the 350 women who attended. Follow-up questionnaires 4–6 months after the individuals attended the class demonstrated that 58% of participants began taking calcium supplements, 32% exercised more, 50% sought the counsel of their primary care physician, 29% obtained a test of bone density, and 33% started a prescription drug for osteoporosis therapy. High-risk participants were more likely to obtain a test of bone density after the program than were low-risk participants. The authors concluded that this community pharmacist-led initiative yielded better bone health behavior in participating women.

Other authors also have discussed the involvement of pharmacists in bone mineral density screening programs in community pharmacy settings, patient and provider resources, potential challenges, and care plan models.^{62, 63}

Future Directions

Limited data exist from controlled trials documenting the effect of pharmacist participation in arthritis or chronic back pain disease management programs. Most of the published information describes the beneficial role pharmacists can play in identifying, preventing, or correcting potential drug-related problems, such as inadequate pain relief, potential drug-drug interactions, and potential adverse drug effects. Likewise, limited information exists from controlled studies establishing the role pharmacists play in achieving improved clinical outcomes for patients with osteoporosis. However, multiple descriptive reports are available that outline successful models of pharmacist participation in osteoporosis disease management activities. Positive outcomes noted from these reports include improved patient knowledge of the disease; improved information exchange with health care providers; and improved use of prevention, detection, and treatment methods. Special attention should focus on patients at highest risk (e.g., post-

menopausal women, patients receiving steroids). These patients should be encouraged to increase dairy intake and take supplemental calcium and vitamin D.

Additional information is needed regarding successful practice models for pharmacists in the management of patients with arthritis, osteoporosis, and chronic back pain. Based on available literature, the development of newer and more proactive models of pharmacist participation in the care of these patients may be warranted. Furthermore, more rigorous evaluation and documentation of the clinical and economic outcomes of patients exposed to such practice models are essential.

Challenges and Opportunities

Challenges to address include adequate training and competency assessment for pharmacists seeking involvement in the care of these patients. In addition, information regarding the cost-effectiveness or cost-benefit of implementing such programs is inadequate. This information is necessary for pharmacists to move forward in the design of strategies that will be financially feasible while improving patient outcomes. The opportunity for pharmacists to be paid for providing care to these patients would provide a financial incentive to community pharmacies and make wide-scale implementation of such programs more attractive.

Recommendations

- Pharmacists need to take a proactive pharmaceutical care approach to assess patients and encourage referral for those with arthritis, with chronic back pain, or at risk for osteoporosis who apparently are not doing well.
- Because effective treatments exist for many patients (particularly those with early disease) to prevent complications that lead to severe pain and disability, patient screening and identification of at-risk individuals is important.
- With respect to chronic back pain, an educational effort to promote good body mechanics with lifting and proper exercise is another opportunity for pharmacists.

Cancer

The overall goal for this focus area is to reduce the number of new cancer cases as well as the illness, disability, and death caused by cancer.

Background

Little literature describes the effect of pharmacist counseling on therapeutic outcomes in oncology patients. Skin, breast, prostate, and oropharyngeal cancers are the primary focus of pharmacists specializing in oncology. However, literature specifically relating their interventions to the prevention of death in patients with cancer could not be identified. Nonetheless, it is in the public's best interest that pharmacists play an active role in this area. A leadership role in this arena is possible and is emerging. Pharmacists have a strong background in pharmacology for both the treatment and prevention of cancer. In addition, pharmacists are able to work collaboratively with other health care professionals to design effective treatment regimens, prevent drug incompatibilities, and minimize the occurrence and severity of adverse events, thereby improving patients' quality of life.

Pharmacy's Position

Pharmacists have a high degree of patient contact because of their presence in the community. As a result, pharmacists are well equipped to provide counseling about a variety of cancers. Many types of cancer are preventable, and a thorough counseling session will often inform patients of the need to take these preventive steps. During regular prescription counseling sessions, patients are encouraged to ask questions related to their disease state and drug therapy. This would be an ideal time for pharmacists to perform a risk assessment for a given patient and recommend applicable preventive steps. Pharmacists working in collaboration with other health care professionals will ensure optimal results.

Documented Impact

Breast Cancer

In one study, community-based pharmacists performed risk assessments for breast cancer on 188 adult women and characterized them as high risk (5-yr risk \geq 1.7%) or low risk (5-yr risk $<$ 1.7%) by using a validated risk-assessment instrument (Gail Model).⁶⁴ All women were asked about their compliance with proper breast cancer screening techniques as issued by the American Cancer Society. Where necessary, pharmacists reviewed these techniques with the women and provided them with an instruction card. A follow-up telephone call was made to

140 of these women after 6 months to determine whether they were performing breast self-examinations (BSEs).

Women performed BSEs more often in the 6 months after the breast cancer counseling than they did before meeting with the pharmacist. After the intervention, 56% of women were performing regular BSEs compared with 31% at baseline ($p < 0.001$). Sixty percent of women performed BSE at least once after counseling with the pharmacist, compared with 20% of women before counseling ($p < 0.005$). Women's confidence in performing BSE also increased after their discussions with a pharmacist. Clinical breast examinations by a health care professional increased from 86% to 91% in women older than 40 years. This variable reached statistical significance (from 81% at baseline to 97% at the 6-mo follow-up) in women aged 40–49 years who had not previously had a clinical breast examination performed by a health care professional.

Tools that pharmacists can use to properly counsel patients at risk for breast cancer have been published.^{65–67} As a member of the health care team, pharmacists also play a vital role in the treatment of patients with existing breast cancer.^{68–71}

Oropharyngeal Cancer

Community pharmacists appear to have underdeveloped skills for referring patients with oral carcinoma to a dental or medical health care professional.⁷²

Prostate Cancer

Two guidance articles were written to provide pharmacists with additional skills to counsel patients with prostate cancer.^{73, 74}

Skin Cancer

Pharmacists are provided counseling targeted at skin cancer prevention, although the outcomes of these services have not been evaluated.^{75–78}

Future Directions

At the time of this writing, there were 277 board-certified (Board of Pharmaceutical Specialties) oncology specialists around the world.⁷⁹ To have a meaningful effect on the above-specified objectives, pharmacists who are actively engaged in oncology clinical practice should publish the results of their interventions.

Challenges and Opportunities

Much of the published literature focuses on pharmacists practicing in community settings, whereas many pharmacists with advanced qualifications in oncology (e.g., residency and/or fellowship training, board certification) practice solely on an inpatient basis, often in academic or research positions. Some pharmacists may be hesitant to attempt to provide this service because of inadequate knowledge of the process on how to market and institute those services. Those serious about seeking professional recognition and payment for their services should seek to advance their clinical skills and should consider board certification.

Recommendations

- Professional pharmacy organizations should help interested pharmacists improve their practice through advances in research, continuing education programs, and special interest groups to foster collaboration among professionals.
- Professional pharmacy organizations should continue to support the endeavors of pharmacists in oncology practice with positive public relations messages to the consumer and other health care professionals.
- Professional pharmacy organizations should continue to validate and recognize distinguished leaders in oncology practice.
- Professional pharmacy organizations should seek to support payment for pharmacy services in this specialty.
- Pharmacists who practice in oncology pharmacy should be made aware of and encouraged to pursue board certification by the Board of Pharmaceutical Specialties.

Chronic Kidney Disease

The overall goal for this focus area is to reduce new cases of chronic kidney disease (CKD) and its complications, disability, death, and economic burden.

Background

The objectives for this section are as listed in Table 2. With the exception of objectives 4-4, 4-5, and 4-6, all are candidates for pharmacists to take an active and, in some cases, even a leading role.

The number of new cases of CKD has continued to rise during the past 15 years, with a decline in

the death rates from other diseases, especially cardiovascular diseases.⁸⁰ Kidney disease develops and progresses more rapidly to end-stage renal disease (ESRD) in people with chronic health problems (such as type 1 or type 2 diabetes mellitus or hypertension) or with a family history of genetic kidney diseases.⁸¹ Also, individuals with microalbuminuria, proteinuria, and/or an elevated serum creatinine level are at increased risk for development of serious cardiovascular disease complications. As this task force has identified both high blood pressure and diabetes as category 1 objectives, it is a logical extension that the prevention and management of CKD should become an active role for the pharmacist.

Pharmacy's Position

Through their position in the community, and secondarily within health systems, pharmacists are distinctively qualified to play a direct role in the clinical management and prevention of renal disease. According to a survey, more than 823 million outpatient visits to clinicians occurred during 2000, and in two thirds of all visits the patient received one or more drugs, totaling approximately 1.3 billion prescriptions.⁸² In this survey, cardiovascular or renal drugs were prescribed at 15% of office visits (~192,198,000 prescriptions). Of interest, of the 20 most frequently prescribed drugs in office practices, caution in dosing is urged in 45% (9 drugs) for patients with CKD.

This large number of new prescriptions, combined with existing pharmacotherapies, exceeds 2.7 billion prescriptions annually. Drug-related problems associated with inappropriate dosing occur in individuals with renal insufficiency or failure, and pharmacists have documented positive outcomes through drug management and other innovative programs for this population.⁸³⁻⁹⁶

Documented Impact

Dosage-Adjustment Services and Care of Patients Receiving Potentially Nephrotoxic Drugs

Renal function can deteriorate with aging or as a result of hypertension or diabetes, and renally excreted drugs can accumulate if not dosed properly. Hematologic, neurologic, renal, and other toxicities may result. Most often, these adverse effects are limited in duration, but on occasion irreversible problems may result.

Patients whose renal function is already compromised are at increased risk for both renal and long-term toxicity. Failure to take into account declining renal function is one of the most common causes of drug dosing errors.^{97, 98}

To help avoid such toxicities, pharmacists have developed a variety of renal dosing programs, mainly hospital based. Most of these programs have been designed to target specific drugs that are excreted renally and most likely to cause problems, examining records for all patients taking such drugs,^{81, 99, 100} or they have been designed to review the complete drug profile of patients whose creatinine clearance decreases below a certain level (usually 50 ml/min).^{86, 101–104}

These programs have yielded documented cost savings, avoidance of adverse events and toxicities, and eventual alteration of prescribing behavior to reflect greater sensitivity to the need for drug dosage modification in patients with renal dysfunction.^{103–107} Computerized pharmacy systems have greatly improved the pharmacist's ability to review drug profiles of individual patients at the time of order entry and intervene when a dosage adjustment is warranted based on the patient's kidney function, with cost savings.^{108–111}

Renal dosing services have been successful at lowering the number of dose-related adverse events.¹¹² Many of these programs focused on antibiotics that are excreted renally (e.g., aminoglycosides). Given that aminoglycoside toxicity is both duration dependent and dose dependent, one successful system shown to limit nephrotoxicity tracked the duration of therapy in hospitalized patients.⁸¹ Pharmacist therapeutic drug monitoring for vancomycin also led to decreased renal toxicity.¹⁰⁰ Pharmacist-implemented renal dosing systems for enoxaparin have been successful in decreasing the rate of bleeding.¹¹³ Pharmacist-initiated interventions for renal dosing of imipenem-cilastatin were well accepted by physicians and can reduce adverse events related to the central nervous system.^{114–116}

Renal dosage monitoring programs have enjoyed a generally high level of approval, with prescribers' acceptance of suggested interventions typically 60–99%.^{104, 117–120} Although most programs are hospital based, programs also have been described in the home health care (73% acceptance rate) and nursing home (84% acceptance rate) settings.^{121, 122} A pilot program based in a community pharmacy also has been reported, and the authors observed that prescribers responded favorably to pharmacists' recommendations.¹²³

Management of Anemia in Patients with Renal Disease

Although management of anemia in patients undergoing dialysis is not specifically included in the Healthy People 2010 objectives, this represents an important area of pharmacist involvement and is relevant to objective 4-2 (reducing cardiovascular deaths in those with CKD). Patients with CKD, especially those undergoing hemodialysis or peritoneal dialysis, are at high risk of anemia with its associated decreased quality of life and increased morbidity. Anemia may be present in early CKD and is not limited to patients undergoing dialysis. Anemia increases the risk for cardiovascular disease such as left ventricular hypertrophy.¹²⁴ In addition, morbidity and mortality are lower when hematocrit values decrease within the target range of 33–35% recommended by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative.¹²⁵ Pharmacists play an important role in this area, working in either pharmacist-managed epoetin programs or on multidisciplinary teams.^{126, 127}

In an analysis of factors influencing management of anemia, the 1997 ESRD Clinical Performance Measures Project emphasized the importance of dosage and route of administration for both epoetin and iron.¹²⁸ The project also identified specific areas in which pharmacists could enhance their role in a multidisciplinary team caring for patients undergoing hemodialysis. Pharmacist implementation of epoetin dosing programs also has improved iron status monitoring of patients undergoing hemodialysis.^{91, 129} In a pharmacist-managed outpatient anemia project for patients with CKD who were undergoing hemodialysis, pharmacist-based management was as effective as physician-based management, with an overall reduction in the amount of erythropoietin used.⁹⁴ Pharmacists have developed procedures to improve the use of epoetin, including measures to increase efficiency and decrease wastage.¹³⁰ Cost savings, with improved iron status, more efficient use of epoetin, and improved maintenance of target hematocrit range have been demonstrated.^{91, 131, 132}

Management of Patients Undergoing Dialysis

In addition to improved anemia management, pharmacists' interventions have improved the care of patients undergoing hemodialysis in other ways. Given the key role that drugs play in the health of patients undergoing dialysis, their

understanding of and adherence to drug regimens are crucial. Pharmacists' activities in hemodialysis units improved patient knowledge of and compliance with drug regimens; interestingly, these effects reversed in the absence of pharmacist participation.¹³³ Pharmacist-managed vancomycin monitoring led to an improved percentage of therapeutic serum concentrations, but with fewer overall blood tests needed.¹³⁴ Others have described the pharmacist's role in identifying and solving a variety of drug-related problems in patients undergoing dialysis, including avoiding interruption in therapy during hospitalization.^{135, 136}

Pharmacists' interventions in patients undergoing hemodialysis have been shown to be clinically significant, with most of the pharmacists' recommendations being accepted.^{87, 89, 90} In one study, pharmacists' interventions were independently evaluated by two different clinical pharmacists with expertise in nephrology pharmacotherapeutics. Thirty-five percent of interventions were related to preservation of major-organ function, 62% improved the quality of care to acceptable standards, and 90% resulted in positive patient outcomes.⁹³

Although not specifically alluded to in Healthy People 2010, the issue of skeletal health, particularly renal osteodystrophy and osteoporosis, is receiving much needed attention. According to the National Kidney Foundation, many patients with kidney disease are at high risk of renal bone disease. Management often involves drug therapy and requires careful monitoring of patients, care to which pharmacists have contributed.^{95, 137} Such management includes treatment with diet, phosphate binders, and vitamin D products.^{91, 138} Pharmacy-managed erythropoietin programs have been expanded to include the dosing of calcitriol, which is crucial in the management of renal osteodystrophy.¹³⁹ A distinct contribution of pharmacy also has been evident in a collaborative effort between ESRD Network 11 and a group of academic nephrology pharmacists to assess the quality of bone disease protocols in use by dialysis facilities throughout the Network. The assessment was based on an eight-point scale including factors such as laboratory monitoring of calcium, phosphorus, and parathyroid hormone levels and use of vitamin D products, dietary control, and phosphate binders. Proper management in this area is not only crucial for skeletal health, but also relevant to the specific Healthy People 2010 goal of decreasing cardiovascular disease in

patients with CKD. This is because the risk of coronary artery calcification is increased in patients with CKD, and the mortality rate is increased in these patients who have hyperphosphatemia, elevated calcium-phosphorus product, and increased parathyroid hormone.¹⁴⁰

Care of Patients with Renal Transplants

Pharmacists' contributions to the care of patients with renal transplants relate to Healthy People 2010 objectives 4-1 (decreasing the number of cases of ESRD) and 4-2 (decreasing cardiovascular mortality in patients with CKD). Pharmaceutical care designed to maintain graft function contributes to objective 4-1.¹⁴¹ Direct patient services provided by a pharmacist on a renal transplant team were very well accepted by physicians and were associated with a significant potential impact on care and considerable cost savings.⁸⁴ Many of the pharmacists' patient care recommendations related to management of hypertension or hyperlipidemia, crucially important issues in this population in whom cardiovascular disease is associated with high morbidity and mortality.¹⁴²

Prevention of Renal Disease and Cardiovascular Complications in Patients with Diabetes or Hypertension

Critical keys to minimize the risk for development of CKD are the optimal management of diabetes or high blood pressure. Management of hypertension is the most important strategy to minimize the development or progression of renal disease.¹⁴³ Pharmacists in diverse settings that include hospitals, ambulatory clinics, nursing homes, large managed care organizations, and community pharmacies have developed many programs to help patients best improve management of diabetes and hypertension.¹⁴⁴⁻¹⁴⁷ This is covered in more detail in other sections of this report. Only a few items will be highlighted here. It is important to recognize that pharmacists' contributions to short-term improvement in glycemic or blood pressure control are relatively straightforward to assess. However, progression of kidney disease typically occurs with long-standing hypertension or diabetes over many years. Thus, documenting the contributions of pharmacists to preventing progression of kidney disease in patients with hypertension or diabetes is very difficult.

Multiple opportunities exist for pharmacists to improve care of diabetic patients, including considerations of altered insulin activity; effects of immunosuppressive agents in those with organ transplants; relationship between diet, exercise, and insulin; monitoring techniques; skin and foot care; and management of hypo- and hyperglycemic reactions.^{148–150} Given the high risk of cardiovascular disease faced by many diabetic patients with CKD, special attention to glycemic control in this group is needed to prevent micro- and macrovascular complications. A key contribution by pharmacy was a study of the relationship between short- and long-term glycemic control measures in those with ESRD.¹⁵¹ In reflecting on the pharmacist's role in improving diabetes management, it is important to recognize that renal disease is a key driver of the overall cost of diabetes care, second only to the presence of neurologic disorders.¹⁵² Thus, pharmacists' efforts to optimize the care of patients with diabetes, in particular development or progression of renal disease, are of great economic and practical importance.

The positive effect of pharmacists' clinical services on the outcomes of ambulatory patients with diabetes has been studied.¹⁵³ Patients were randomly assigned to usual clinic and pharmacy care or to usual care plus more extensive pharmaceutical care that included enhanced drug therapy monitoring and patient counseling, periodic review of patient records and discussion with the physician, and referral to the public health nurse as needed. The patients who received more extensive pharmaceutical care had fewer changes in therapeutic regimens, hospital admissions, and medical contacts than did the control group.

A community pharmacy-based diabetes patient-management program included 32 patients followed for 6–12 months within a network of pharmacies.¹⁵⁴ Improvements were found in total and low-density lipoprotein cholesterol levels and in glycosylated hemoglobin for those patients with the poorest glycemic control at baseline.

A larger study took place in 54 community pharmacies and included 675 patients at high risk of cardiovascular events (approximately 43% with diabetes).¹⁵⁵ Patients were randomly assigned to receive pharmacist intervention or usual care. The study was stopped early because those patients assigned to pharmacist intervention had significantly improved cholesterol management (i.e., cholesterol panel ordered by a prescriber,

added or increased dosage of a lipid-lowering agent).

Importantly, Healthy People 2010 objectives for chronic renal failure emphasize that special attention should be given to underserved groups and to those disparately affected by disease. In one study conducted in a free medical clinic, diabetic patients cared for within the pharmacist-implemented program had higher rates of foot and dilated eye examinations and higher frequencies of measurement of glycosylated hemoglobin, fasting lipids, and urinary proteins (by dipstick) than did the general clinic group. Those in the pharmacist-implemented program also had greater decreases in glycosylated hemoglobin.³⁸ One group reported that pharmaceutical care intervention led to improved glycemic control in a group of urban, ambulatory African-American patients with diabetes.¹⁵⁶ This may have special relevance given the prevalence of CKD among African-Americans.

Future Directions

Pharmacists can decrease the rate of development of CKD through patient screenings for hypertension and diabetes to identify individuals who would benefit from diagnosis and treatment by a physician. Once diabetes or hypertension is diagnosed, the pharmacist, through counseling activities, disease state management, and patient monitoring, can have a significant impact to reduce the development of disease complications. The supporting information related to this topic is described in the sections on Diabetes and on Heart Disease and Stroke. Although pharmacists' activities can improve recognition and treatment of those with diabetes and hypertension, it must be appreciated that measuring the long-term impact of these interventions on prevention of chronic complications, such as CKD, is difficult. Additional efforts to link pharmacists' interventions to the achievement of beneficial long-term patient outcomes are needed.

Pharmacists also must be involved in the use of drugs known to cause CKD. The use of pharmacists in drug protocol management of high-risk drugs in the hospital setting has been associated with a 38% reduction in total medication errors and a 36% reduction in errors that resulted in adverse patient outcomes, including kidney failure.¹⁵⁷ Pharmacist dosing of aminoglycosides according to serum concentrations decreases the risk for iatrogenic kidney failure. Other drugs known to cause renal insufficiency (e.g., NSAIDs, amphotericin B,

cyclosporine, cancer chemotherapy) should be monitored for proper dosing and adverse effects. Given the relatively small numbers of nephrology pharmacists and the large numbers of patients at risk for renal disease from drugs (in addition to the risk from hypertension and diabetes), it is crucial that pharmacists in general expand their knowledge of renal disease and the pharmacotherapy implications of CKD. Involvement of pharmacists in the care of patients undergoing hemodialysis would be expected to increase the proportion of patients receiving information on treatment choices and cardiovascular care, as identified in objective 4-3 (Table 2). Pharmacists have a proven record in working with patients receiving hemodialysis or peritoneal dialysis to ensure proper dosing and adherence to drug therapy. By providing drug-dosing guidelines for patients with renal insufficiency, the pharmacist can affect both clinical and economic outcomes. The cost savings generated in the short term is frequently used as justification for pharmacist dosing protocols in the hospital and clinic setting. Continued expansion and cost justification of pharmaceutical care to reduce the risks of cardiovascular disease and other complications such as osteodystrophy are necessary in patients undergoing hemodialysis.

Challenges and Opportunities

Challenges exist for pharmacist involvement in achieving the objectives for the Chronic Kidney Disease chapter of Healthy People 2010, in addition to the challenges documented in the Heart Disease and Stroke and the Diabetes chapters. Although pharmacists were involved in pharmacokinetic consultation in 80% of hospitals in 1998, drug therapy monitoring was reported to occur in only 54% of hospitals.¹⁵⁸ Where it does occur, approximately one third of patients are monitored. Management of drug therapy by protocol is available in 70% of hospitals but involves only about 2% of patients. In another study involving patients undergoing hemodialysis or continuous ambulatory peritoneal dialysis, most patients did not recall all of their drugs, many routinely missed several drugs/month, and only 15% indicated their pharmacist to be their primary source of drug information.¹⁵⁹ Taken as a whole, these studies indicate that pharmacists must strengthen their efforts to improve the care of patients who have or are at risk of renal disease and to publish further studies that document improved patient outcomes resulting

from pharmacist provision of services to these patients.

Recommendations

- A need exists for wider pharmacist involvement in the screening, detection, treatment, and monitoring of hypertension and diabetes as the major effort that would prevent the development of CKD. Improved health care outcomes due to pharmacist activities have been documented in well-controlled trials for these maladies. Increased efforts in these areas by large numbers of pharmacists in a variety of patient care settings hold great potential for reducing the number of new cases of CKD. There are relatively few nephrology pharmacists, and such individuals often are involved with those who already have CKD. Improved communication and collaboration between these experts and pharmacists in the internal medicine, ambulatory care, and other settings has the potential to reduce the number of individuals who will progress to CKD.
- Pharmacists should continue to document their activities on behalf of patients with renal disease and also document improvement in patient outcomes as a result of these activities. Pharmacist monitoring of drug therapy, management of drug therapy by protocol, management of anemia and other complications faced by patients with renal disease, and pharmacokinetic services have been shown cost-effective in a variety of studies.¹⁶⁰ The results of an observational study that used a large national database indicate an improvement in the risk for medication errors and adverse patient outcomes with pharmacist input.¹⁵⁷
- Increased attention is needed to the issue of payment for pharmacist-provided services to patients with renal disease. For patients undergoing dialysis, for whom Medicare benefits are key, payment requires that the health care provider be recognized as such by Medicare. At the time of this writing, pharmacists are not among the health care providers recognized in the Medicare statutes. On a practical level, such restrictions will limit the extent of pharmacist participation in the care of some patients with renal disease.
- Finally, given the large number of individuals at risk for renal disease, it is important that

pharmacists have a good basic and clinical knowledge of issues related to kidney disease. For pharmacists in general, improved education about renal disease will be necessary. The role of drugs in both exacerbating as well as preventing and treating renal disease should be addressed in pharmacy school curricula and postdoctoral training to improve the overall level of care for the large number of individuals with or at risk for CKD.

Diabetes Mellitus

The overall goal for this focus area, through prevention programs, is to reduce the disease and its economic burden and to improve the quality of life for all persons who have or are at risk for diabetes.

Background

Diabetes mellitus is a chronic disease affecting more than 15 million persons in the United States. Approximately 800,000 new cases are diagnosed each year.¹⁶¹⁻¹⁶³ The disease is the seventh leading cause of death in the United States and the leading cause of ESRD.¹⁶⁴ Despite proven secondary and tertiary prevention strategies, the rate of diabetes and diabetic complications is increasing. Direct and indirect costs of treating this disease total \$100 billion annually.^{165, 166}

Pharmacy's Position

Seventeen objectives (Table 2) divided into six categories were developed to address health concerns pertaining to diabetes and its associated complications. Within each category, it is evident that pharmacists are or can be instrumental in providing services to accomplish most of the objectives. Pharmacists are distinctively positioned in the health care system to provide care to patients with diabetes because patient education and pharmacotherapy are hallmarks for treating this disease. In fact, one section of this chapter states "a variety of non-physician health professionals (for example, nurses or pharmacists) can be involved in critical decisions affecting chronic diseases."

Documented Impact and Future Directions

Pharmacists provide diabetes education in accordance with the first Healthy People 2010 objective in multiple practice settings. In a

survey of attitudes toward diabetes, 339 hospital, community, and other pharmacists recorded positive scores in four of nine assessment categories.¹⁶⁷ The category scores indicated that pharmacists have the skills to become diabetes educators, they should be part of the health care team for managing diabetes, and they should be required to have specialized training for providing primary diabetes care. In another survey of community pharmacists, the authors found that 52% provided at least basic diabetes patient education.¹⁶⁸ As of March 26, 2002, 478 pharmacists were Certified Diabetes Educators (CDEs), which accounted for 3.8% of all CDEs (National Certification Board for Diabetes Educators, personal communication, March 26, 2002). In addition, 51 pharmacists recently completed the diabetes certification program through the American Pharmacists Association (APhA) (American Pharmacists Association, personal communication, March 27, 2002). However, many pharmacists who are not specially trained also provide patient counseling and education to patients with diabetes. To accomplish this Healthy People 2010 objective, it will be important for pharmacists to document their educational services provided to patients with diabetes.

Numerous studies have examined the effect of pharmacist-provided diabetes services on disease-related outcomes.^{38, 169-177} Most of the studies documented positive effects on glycosylated hemoglobin. In one study, pharmacists provided diabetes education, drug counseling, drug therapy monitoring, and drug adjustments to 23 patients with type 2 diabetes. These patients were followed for 27 weeks during which time glycosylated hemoglobin decreased 2.2% from baseline ($p=0.00004$).¹⁷¹ Also, 17 patients who received similar services from a pharmacist during a 4-month period had a significant decrease in glycosylated hemoglobin compared with that in the control group ($p=0.003$).¹⁷³ By using glycosylated hemoglobin as a marker for disease improvement, these studies have shown that pharmacists are working toward Healthy People 2010 objectives to reduce macrovascular, microvascular, and metabolic complications of diabetes.

Few studies, however, are well-controlled, prospective trials. The studies contain small numbers of patients and have not been designed to evaluate the pharmacists' impact on morbidity and mortality. Research to examine these outcomes would provide evidence that

pharmacists may be able to reduce the burden of disease related to diabetes and provide progress toward meeting other Healthy People 2010 objectives.

Pharmacists also have worked to accomplish Healthy People 2010 objectives related to laboratory and health care provider services. Several studies have demonstrated that when pharmacists participate in the care of diabetic patients, recommended laboratory monitoring and physician visits for foot and eye examinations are increased.^{38, 175, 177, 178} One author¹⁷⁷ reported that 99% of diabetic patients who received integrated care services with a pharmacist met American Diabetes Association (ADA) standards of care in 2000.¹⁷⁹ In comparison, only 45% of patients in a usual care control group met the ADA standards. Included in the ADA standards were glycosylated hemoglobin and cholesterol determination, as well as annual foot and eye examinations. Although an annual urinary microalbumin determination is a specific objective of Healthy People 2010, no studies have reported improvement in this parameter through pharmacy intervention.

Another Healthy People 2010 objective seeks to increase the proportion of diabetic adults who perform self-monitoring of blood glucose levels at least once/day. In one study, pharmacists' involvement in diabetes care management improved patients' frequency of self-monitoring of blood glucose levels.¹⁷⁴ However, another study found no change in the frequency of self-monitoring among diabetic patients who were enrolled in a pharmaceutical care program.¹⁷⁰ More studies should be designed to test if a pharmacist can increase the frequency of self-monitoring of blood glucose levels at home in accordance with Healthy People 2010. A final objective is to increase the proportion of diabetic adults who take aspirin at least 15 times/month. Although this is an objective for which pharmacists can make a significant impact, no studies have documented that pharmacists increase the use of aspirin among patients with diabetes. This is one area that deserves more focus from pharmacists.

Challenges and Opportunities

The literature indicates that pharmacists provide services to help accomplish several of the Healthy People 2010 diabetes objectives. Many abstracts and presentations have elucidated the pharmacists' roles in the care of the diabetic

patient.¹⁸⁰⁻¹⁹⁷ Pharmacists should strive to conduct high-quality, outcomes-based research and continue to publish information about the role of the pharmacist in the care of patients with diabetes. Additional training may be needed before more pharmacists can become active in the care of diabetic patients. There are several training opportunities available from organizations such as the APhA, American Society of Health-System Pharmacists (ASHP), and Life Scan. Also, pharmacists should seek partnerships with other health professionals to provide collaborative, integrated diabetes care. The complex drug regimens of diabetic patients demand that existing diabetes patient education programs include more pharmacists to help develop and deliver curricula. In addition, diabetic patients should receive at least a biannual drug review from a pharmacist.

Current compensation for diabetes education, however, is not adequate to support a pharmacist's salary. Similarly, there is no payment mechanism for pharmacists to help manage patients with diabetes. Through legislative initiatives and improved credentialing, pharmacists can continue efforts to be recognized care providers. A new credentialing program (Advanced Clinical Diabetes Management) through the American Association of Diabetes Educators and the American Nurses Credentialing Center is available to pharmacists, as well as nurses and dietitians.¹⁹⁸ This credentialing program might provide an avenue by which pharmacists can be recognized providers and receive payment for diabetes management services.

Finally, community pharmacies should form partnerships to disseminate health care messages to patients with diabetes. A significant impact on public health could be realized if a uniform, consistent message could be delivered through our community pharmacies. In many capacities, pharmacists can be leaders working toward the stated goal for diabetes in Healthy People 2010.

Recommendations

- Advocate for pharmacists' recognition as health care providers by Medicare.
- Ensure that payment strategies are sufficient to support a pharmacist's salary.
- Provide and seek out research funding opportunities.
- Publish reports and papers recognizing pharmacists' roles in caring for patients with diabetes.

- Strive to form collaborative relationships with other health care professionals.

Family Planning

The overall goal for this focus area is to improve pregnancy planning and spacing and to prevent unintended pregnancy.

Background

The family planning objectives of Healthy People 2010 focus on the prevention of unintended pregnancy through pregnancy-prevention education, contraceptive use, elimination of contraceptive failures, use of emergency contraception, targeting the at-risk population of adolescents, and provision of insurance coverage for contraceptive supplies and services. The cost of an unintended pregnancy is high socially, economically, and medically. The mother in an unintended pregnancy is less likely to seek prenatal care in the first trimester, less likely to breastfeed, and more likely to expose the fetus to harmful substances. The unintended child has reduced educational attainment and employment opportunities possibly related to an increased risk of being abused or not having a healthy development. The Healthy People 2010 objectives do not address abstinence education for adolescents and natural methods of family planning, which for a segment of the population are the only morally acceptable means of preventing unwanted pregnancies.

Pharmacy's Position

Family planning has long been an important health care area in which pharmacists are active. Condoms, spermicides, home pregnancy tests, and basal thermometers have always been sold at the community pharmacy. The first purchase of these items is frequently made at a pharmacy, although follow-up purchases may occur at a wide variety of locations. Prescriptions for diaphragms and oral contraceptives are filled at a pharmacy. Also, pharmacists provide emergency contraception on prescription from a health care provider or, in some states, under protocol through collaborative practice.

The pharmacist's knowledge of the products used in family planning places him or her in a position to provide education to the consumer. Those seeking to ask questions about use, effectiveness, or adverse effects of contraceptives

frequently turn to the pharmacist because of their public accessibility. Unintended pregnancies that occur despite use of a reversible contraceptive method are believed to be due primarily to inconsistent and/or improper use. The pharmacist, by virtue of training and access, is well positioned to advise consumers about family planning methods and serve as a primary provider of related health services.

Pharmacists are able to provide several types of hormonal contraceptives through collaborative practice programs, including oral contraceptives, transdermal patches, and vaginal rings. A proposed component of this service could be administration of contraceptive injections in states where this is allowed, thus saving a trip to the physician's office.

Documented Impact

Pharmacists routinely provide education and counseling about over-the-counter items available for family planning. Pharmacists have documented significant activities in family planning since the 1970s. Notably, pharmacies are used as prime locations for family planning programs in developing countries such as Colombia, Bangladesh, Ghana, South Africa, and India.¹⁹⁹

The APhA adopted a resolution in support of pharmacists' provision of emergency contraception. In addition, they have published a comprehensive continuing education program that can be used to prepare pharmacists to provide emergency contraception.²⁰⁰

The recent expansion of the pharmacist role in emergency contraception through collaborative practice agreements in Washington State has been documented.^{201, 202} A pilot project to train pharmacists, develop collaborative drug therapy agreements, standardize a protocol, obtain consent, and provide media coverage resulted in pharmacists initiating more than 1000 emergency contraception prescriptions/month. Although the duration of follow-up was inadequate for definitive conclusions, it was estimated that the program may have prevented 50 unintended pregnancies/month.²⁰² A cost model identified savings to payers of \$48–158 in unintended pregnancy costs/woman having unprotected intercourse.²⁰³ Furthermore, the delays associated with obtaining emergency contraception from a physician as compared with a pharmacist would be expected to impact its effectiveness. This variable was not included in the cost and outcome model.

Future Directions

Pharmacist-provided emergency contraception programs are under way in California and Alaska, the United Kingdom, and the Canadian province of British Columbia. At least 29 states allow pharmacists to prescribe directly or adjust drugs through collaborative practice agreements similar to those in Washington State.²⁰⁴ Emergency contraception protocols could become a routine part of pharmacist collaborative practice in those states until such time as the products are approved for use without a prescription.

Community pharmacies often stock the supplies needed for family planning, including the products used in emergency contraception. Pharmacists who offer such services should maintain a high degree of competency in the area of family planning and be willing to provide these counseling services for their patients in the primary care clinic and community pharmacy settings. Pharmacists who decline to provide such services based on religious or other beliefs should be free to do so.

Challenges and Opportunities

States where pharmacists do not have collaborative practice should amend the pharmacy practice act to include this practice. Third-party payers should implement payment mechanisms for pharmacist counseling and related services. Prescribers must be made aware of pharmacist-provided services, supplies, and collaborative practice agreements.

Recommendations

- Some pharmacists advocate the establishment of emergency contraception programs in all states where collaborative practice models exist. Others oppose such programs and hold personal beliefs that preclude their participation in such practices. This is a personal matter that should be left to the individual pharmacist.
- Establish collaborative practice mandates in all states.
- Lobby insurance companies for coverage of pharmacist-provided family planning services.
- Develop programs to provide counseling (including abstinence promotion) to targeted populations (specifically adolescents) and document the outcomes associated with this activity.

- Document conclusively the overall impact of pharmacist-provided emergency contraception programs.
- Document the overall impact of pharmacist-provided hormonal contraception through collaborative practice programs.

Health Communication

The overall goal for this focus area is to use communication strategically to improve health.

Background

The Overview of the Healthy People 2010 section on Health Communication begins with this statement, "Health communication encompasses the study and use of communication strategies to inform and influence individual and community decisions that enhance health." Eight specific areas are identified where health communication can contribute to all aspects of disease prevention and health promotion: health professional-patient relations; individual's exposure to, search for, and use of health information; individual's adherence to clinical recommendations and regimens; the construction of public health messages and campaigns; the dissemination of individual and population health risk information (risk communication); images of health in the mass media and the culture at large; education of consumers about how to gain access to the public health and health care systems; and development of "telehealth" applications.

Review of the areas listed above identifies a strong, active role for pharmacy in providing support and solutions to the critical need for effective communication about health and the impact this communication would have on reducing health disparities. The attributes of effective health communication are listed in the Healthy People 2010 report. It is important to keep these attributes in mind, as a great deal of misinformation exists in the public arena on issues of health, disease, prevention, and treatment. There is a health communication component to most, if not all, of the focus areas identified in the report.

Pharmacy's Position

Pharmacists are in a unique position to support the goals of Healthy People 2010 through communication of health information beyond that of drug therapy or disease state. The

accessibility of pharmacists provides an important interface between communities and health-related information.

Documented Impact

The nature and extent of research and evaluation in health communication, focusing mainly on the skills needed by pharmacists, have been summarized previously.²⁰⁵ Communication models have been discussed in the context of patient counseling,²⁰⁶ and strategies to improve communications between health care professionals and older clients have been reported, including how to improve collaboration and present clear messages that are mutually understood.²⁰⁷ Success, in one author's view, "requires tailoring strategies to individual clients rather than basing communication on general assumptions about clients."²⁰⁷ Key to the goals of Healthy People 2010, a survey by the Commonwealth Fund showed that for a range of health care quality factors such as patient-provider communications, cultural and linguistic barriers, and access to health care and insurance coverage, minority Americans were not faring as well as Caucasians.²⁰⁸

Health communication activities have contributed to the promotion of health and disease prevention in a number of areas. Several reports have examined the effect of training health professionals and patients in communication skills on improved interpersonal and group interactions in clinical situations involving provider-patient, provider-provider, and members of health care teams.^{209, 210} Public education campaigns are effective means of disseminating health messages. These campaigns are designed to promote healthy behavior through information, increasing awareness, motivation, and changing attitudes of individuals.²¹¹⁻²¹³ The methods used to convey these messages are mass communication through public service announcements on radio, television, and billboards and printed information in pamphlets, newspapers, and magazines. Increasingly important is the role that computer and Internet-based technologies play in delivering information and messages. These methodologies are flexible and can target messages to specific audiences and populations. The interactivity allows for active participation by the public.^{210, 214, 215} An emerging area in health communication involves programs designed to support community-centered prevention.²¹⁶ As described in the Healthy

People 2010 document, "community-centered prevention shifts attention from individual to group-level change and emphasizes the empowerment of individuals and communities to effect change on multiple levels."

Future Directions

A review of the Healthy People 2010 objectives suggests that accomplishing these objectives will require an effort that goes beyond the effective use of health communication. Deep-rooted, systemic problems of poverty, lack of access to health care, and poor environmental conditions will not change as a result of improved health communication. The Healthy People 2010 report suggests that comprehensive health communication programs "include a systematic exploration of all the factors that contribute to health and the strategies that could be used to influence these factors." Appropriate actions to maximize health can result if individuals are better able to understand their own and their communities' needs.

Reaching the goal of reducing or eliminating health disparities by 2010 will require a multidimensional approach to health promotion and the investigation of new paradigms to transmit the message. Pharmacists have been underutilized in community-wide efforts. In instances where pharmacists have been involved, the role is often directly related to drug issues and not the broader approach to health.

Challenges and Opportunities

Actions by pharmacists to promote and provide immunizations are evidence that a major public health role for pharmacists is needed and welcomed and has a positive impact on a community's health. It is important that pharmacists and pharmacies be seen by the public as centers for health promotion, disease prevention, and drug information. This will place the profession in a more visible position to move to a greater (and complementary) role in improving the nation's health.

Not all pharmacists are equally equipped educationally to take on these new opportunities and responsibilities. The resources necessary to accomplish this education may be lessened through partnerships between pharmacy and the public health enterprise including schools of public health, professional associations, and the Centers for Disease Control and Prevention (CDC).

Recommendations

- Pharmacists, pharmacy organizations, pharmacy education, and pharmacy institutions (community, hospital, clinics, etc.) should ensure that they are active participants in their communities. Although national strategies are important, they must be adapted to the local community. Pharmacy must participate actively in discussions of community approaches to issues such as obesity, smoking cessation, substance abuse, violence, preventive screenings, immunizations, and so forth. Professional organizations should develop workshops and other types of programs to educate pharmacists to assume these leadership roles.
- Colleges of pharmacy should provide education and training for their students in health communication and the translation of this resource into action. It is suggested that elements of effective health communication be developed throughout the didactic and experiential curricula. The training must include experience in communication with other health professionals, employers, government, and the community.
- Partnerships should be forged with other health-related and community-based organizations including the American Public Health Association, departments of public health, health care insurers, and the CDC. Although the individual practitioner ultimately will be responsible for delivering a large part of the communication content, it will fall on the pharmacy organizations and educational institutions to drive this issue.
- Pharmacists should be actively engaged in community-based research projects that focus on community health.

Heart Disease and Stroke

The overall goal for this focus area is to improve cardiovascular health and quality of life through prevention, detection, and treatment of risk factors; early identification and treatment of heart attacks and strokes; and prevention of recurrent cardiovascular events.

Background

The Healthy People 2010 goals related to heart disease and stroke are to be accomplished through management of risk factors, early detection

and treatment, and secondary prevention. The modifiable risk factors specifically addressed are hypertension and hypercholesterolemia. In addition, the objectives list the provision of cardiopulmonary resuscitation (CPR) when there is a witnessed out-of-hospital cardiac arrest.

A number of interventions and activities that are known to be effective in reducing heart disease and stroke have substantial overlap with other Healthy People 2010 focus areas. These include smoking cessation, weight management, and diabetes control. Because of this overlap, a gaps analysis for these areas is not provided here. The reader is referred to the Healthy People 2010 focus areas on tobacco use, diabetes, and nutrition and overweight. Management of these conditions by pharmacists can reduce cardiovascular risk.

Pharmacy's Position

Pharmacists have been involved in all phases of cardiovascular risk factor modification since the early 1970s through clinics, hospitals, managed care organizations, and community pharmacies. A recent survey showed considerable interest among community pharmacists in providing health education and cardiovascular disease prevention services.¹⁷ Pharmacists are well positioned to provide lipid and hypertension screening and detection programs in community pharmacies. By targeting patients taking certain drugs (i.e., β -blockers, thiazide diuretics, hypoglycemic agents, sublingual nitroglycerin), which can be identified through community pharmacy databases, the likelihood of detecting elevated cholesterol values is high.²¹⁷ Pharmacists can provide disease state management of hypercholesterolemia, hypertension, and heart failure in community pharmacy or clinic settings. In addition, hospital pharmacists are active in early treatment of acute coronary syndromes and stroke.

Pharmacists should be trained in CPR. Current standards of the Accreditation Council for Pharmacy Education for colleges of pharmacy require students to be capable of providing "first care." This is interpreted by many schools of pharmacy to include training in CPR, basic life support, and use of automatic external defibrillators.

Documented Impact

Heart Disease

Thrombolytic Therapy. The use of artery-

opening therapy within 1 hour of onset of chest pain due to a heart attack is central to improving quality of care at many hospitals. One type of artery-opening therapy is treatment with thrombolytic agents such as alteplase. Many factors conspire to prevent patients from receiving thrombolytic therapy within 1 hour from onset of chest pain. The hospital pharmacist can participate in implementing clinical pathways to increase utilization rates and reduce “door-to-needle time” for those with clear indications for therapy.²¹⁸

Heart Failure. Many studies have documented the activities of pharmacists to reduce hospital admissions for heart failure.⁴⁷ These activities have involved patient counseling, monitoring after hospital discharge, patient risk assessment, and/or recommendations for drug changes and referrals to other health care providers.^{219–223} Most directly, the pharmacist is able to improve use of, optimal dosing of, and compliance with angiotensin-converting enzyme inhibitors, vasodilators, and β -adrenergic blocking agents.^{224, 225} Pharmacists also were successful in improving function and quality of life for patients with heart failure in a three-center study in Ireland.²²⁶ Studies of a pharmacist and nurse team that provided home visits in Australia revealed significant decreases in rehospitalization for heart failure.²²⁷

Adherence and Compliance with Cardiovascular Agents. Adherence to and compliance with drug therapy and lifestyle changes were cited in the Healthy People 2010 chapter as important factors in achieving long-term control of coronary heart disease risk factors. The pharmacist has been identified in multiple studies as a key health care professional able to increase compliance and adherence.^{228, 229}

Stroke

Although anticoagulation therapy for prevention of embolic stroke in patients with atrial fibrillation or mechanical heart valves was not specifically addressed in this chapter, it is known that such treatment reduces risk of embolic stroke. The advantages and cost-effectiveness of pharmacist-conducted clinics to manage patients taking anticoagulation therapy for this indication and others have been well documented.^{230–233} Studies in multiple settings across the country attest to the generalizability of this practice. One group of authors reported a significantly lower

rate of hospitalization for patients managed by a pharmacist in an anticoagulation clinic compared with a control group not managed by pharmacists, with a net savings in hospitalization costs/year of more than \$200,000 (1985 dollars).²³¹ Another study found the savings associated with a pharmacist-managed anticoagulation clinic to be \$162,058/100 patients/year.²³³

Blood Pressure

Significant impact in single-site studies for screening, detection, and treatment of hypertension has been reported since the 1970s.²³⁴ Blood pressure control was improved when community pharmacists assisted with patient education, blood pressure monitoring, and drug therapy management. Quality of life was also improved in patients followed by a pharmacist for 4–6 months.^{235, 236} Integrated health systems like the Veterans Affairs medical centers, Indian Health Service, and staff model health maintenance organizations have shown the beneficial effects of pharmacist-provided services in hypertension management.²³⁷ A study involving 10 Veterans Affairs medical centers and one university hospital showed a significant improvement in blood pressure management in the pharmacist-treated group compared with the control group.^{238, 239} This benefit was coupled with fewer visits to other health care providers, a trend toward fewer hospitalizations, and improved patient satisfaction.

Cholesterol

In the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP), the authors evaluated a community pharmacy-based screening and intervention program in Canada through a randomized, controlled trial.^{176, 240} The program led to a significant reduction in cardiovascular risk in the intervention group compared with the control group. A multicenter study of pharmacist provision of pharmaceutical care from Veterans Affairs medical centers showed significant improvement in total and low-density lipoprotein cholesterol values compared with standard care.⁴³

Rates of persistence and compliance with drug therapy were more than 90% in an observational study of 26 community pharmacies providing pharmaceutical care for patients with hypercholesterolemia.⁴¹ Pharmacists in the hospital setting are successful in working with teams to get appropriate patients tested and treated for secondary prevention of heart disease.²⁴¹ These

studies demonstrate that pharmacists are able to improve total cholesterol scores, reduce the proportion of adults who have not had their cholesterol checked, reduce the proportion with high total cholesterol levels, and increase the proportion of individuals with coronary heart disease who reach their target low-density lipoprotein cholesterol level.

Summary

Pharmacy has documented the effect of pharmacists on screening, detecting, and treating hypercholesterolemia in many single-site and several multicenter trials; documented the effect of pharmacists on screening, detecting, and treating hypertension in many single-site trials and one multicenter trial; documented the effect of pharmacist-run anticoagulation clinics in many single-site trials; documented the effect of pharmacists on reducing admissions for heart failure in several single-site trials; established training programs for pharmacists in hypercholesterolemia, anticoagulation, and heart failure management; required pharmacy students to be educated in CPR; participated in quality improvement projects to improve use of thrombolytic therapy; and published a call to action for pharmacist participation in achieving the Healthy People 2010 goals for hypertension.

Future Directions

Multicenter studies with a design similar to those performed for hypertension and hypercholesterolemia that evaluate the effect of pharmacist management of heart failure would help to complete the needed documentation for this service area. The effect of pharmacists in the areas of hypertension, hypercholesterolemia, and anticoagulation has been clearly documented. This foundation should be used to establish pharmacist-provided disease state management programs in these areas as a standard of practice throughout the country. Administrators, physicians, health policy decision makers, and the general public need to be made aware of the benefits of these services.

Challenges and Opportunities

Pharmacists practicing in the community and in primary care clinics across the country must be competent to provide services related to hypertension, hypercholesterolemia, heart failure, and anticoagulation. Pharmacists in states that do not have collaborative practice authority

should work to amend their pharmacy practice acts to enable this type of practice. Pharmacists need to have third-party payers recognize and pay for the provision of these beneficial services. Prescribers must be made aware of pharmacist-provided services and opportunities for collaborative practice agreements.

Unfortunately, one study found that only 41% of pharmacists maintained their competency in basic life support 1–5 years after graduation from pharmacy school.²⁴² Less than 10% of pharmacists in this survey reported providing mouth-to-mouth resuscitation, mask breathing, or external chest compressions. Pharmacists seem ambivalent about the value of basic life support to their current practice.

Recommendations

- The contributions of pharmacists should be publicized toward achievement of the Healthy People 2010 goals and objectives for hypertension, hypercholesterolemia, and heart failure to health policy decision makers at the state and national levels.
- Pharmacists and pharmacy organizations should campaign directly to stakeholders to include pharmacist-provided services that have been shown to improve patient care.
- Collaborative drug therapy management by pharmacists should be practiced in all states.
- Payment of pharmacists' services related to drug therapy management should be advocated.
- Well-designed, multicenter studies must document the effect of pharmacists on health outcomes for patients with heart failure.
- Pharmacists who practice in the area of cardiology should be made aware of and encouraged to seek added qualification recognition by the Board of Pharmaceutical Specialties.
- Additional training programs for management of heart failure should be implemented.
- Training on disease-state management for hypertension, hypercholesterolemia, heart failure, and anticoagulation services should be provided to all pharmacists and pharmacy students.
- The proportion of pharmacists with skills in basic life support and use of automatic defibrillators should be increased.

Human Immunodeficiency Virus

The overall goal for this focus area is to prevent human immunodeficiency virus (HIV) infection and its related illness and death.

Background

Given their background, training, position in the community, and interest, pharmacists can help achieve several Healthy People 2010 objectives related to HIV. For those persons with HIV, the infectious diseases–trained clinical pharmacist plays a crucial role in disease management and can improve health status and quality of life. This role encompasses Healthy People 2010 objectives relating to increasing the proportion of individuals given treatment according to guidelines, prolonging the interval between infection with HIV and diagnosis of acquired immunodeficiency syndrome (AIDS), prolonging the interval between AIDS diagnosis and death from AIDS, and counseling on and testing for HIV in state prisons.

For the public at large, pharmacists can help prevent the spread of HIV in three ways: by working to optimize therapy for HIV-positive individuals (because those receiving optimal treatment and those with low viral load are less likely to spread disease); by promoting condom use to reduce transmission of the virus in the population; and by promoting use of sterile needles by those taking illicit drugs. These roles encompass Healthy People 2010 objectives that relate to decreasing AIDS among persons who inject drugs, decreasing the number of new AIDS cases, and promoting condom use.

Pharmacy's Position

Infectious diseases pharmacists possess expertise with the complicated drug regimens used for antiretroviral therapy typified by a high number of drugs, the necessity for strict timing and adherence, and the potential for drug interactions and adverse drug events.^{243–251} This is especially important because lack of adherence to therapy can quickly lead to viral resistance. In one study, HIV patient focus groups identified eight common barriers to adherence to highly active antiretroviral therapy.²⁵² Pharmacists could help greatly with six of the eight barriers: frequency and severity of adverse effects, conflicts with daily routines, dietary requirements, frequency of taking the drugs, number and dosage of the drugs, and pharmacy refills.

Also important is the attitude of other health care professionals toward pharmacist participation in the care of patients with HIV or AIDS. In a study of HIV case managers, it was found that 81% desired increased collaboration with pharmacists, 80% were interested in pharmacies

that specialize in HIV, and 64% were supportive of payment for pharmacists to provide HIV drug counseling.²⁵³

Finally, pharmacists' attitudes, their place in the community, and their accessibility position them to play a positive role in curbing the spread of HIV. In addition to their obvious potential to promote condom use, studies have shown that community pharmacists have a positive outlook regarding their role in HIV prevention and are overwhelmingly interested in providing education about preventive strategies through their practice settings.^{17, 254, 255} Pharmacists are also willing to participate in programs that provide sterile syringes and needles to those who take intravenous drugs, in order to prevent the spread of infectious diseases among this group.^{18, 256, 257} Finally, the accessibility of pharmacists in the community can contribute to the promotion of safer health practices among underserved populations and adolescents.

Documented Impact

The following gives examples, rather than an exhaustive list, of the many contributions made by pharmacists to HIV prevention and treatment. In multidisciplinary HIV-AIDS clinics, pharmacists take drug histories and provide patient education, individual patient consultation, and counseling.^{245–248, 250, 251, 258} They monitor efficacy and toxicity of antiretroviral and other drug therapy, manage drug interactions, and provide continuity of care to patients in hospitals and the community. Pharmacists provide triage and manage other health problems that occur in patients attending HIV clinics. They participate in formulary decisions, education of other health care providers, and research. Such clinic settings also provide training sites for pharmacy students and residents.

An innovative program has been established in the Texas prison system, where televideo counseling is carried out for 133,000 inmates, many of them with HIV. In this program, a pharmacist collaborates with a nurse to review patient medical records and to assess and counsel patients with HIV by way of a televideo linkup.²⁵⁹

Pharmacists also participate in needle exchange programs, which have been shown to reduce HIV risk and are cost-effective.^{256, 260, 261} Another program, organized by faculty and student volunteers, provided counseling about drugs to medically indigent patients, made recommendations regarding patient's therapies to

physicians and medical students, carried out brown-bag programs, and provided HIV testing and referral.²⁶² There are also community pharmacy-sponsored programs for patients with HIV that offer counseling and other services. These programs do not appear to have been formally evaluated, and at this point appear to be present in a small number of outlets with limited services. Finally, educational efforts for pharmacists include establishment of an HIV-AIDS pharmacotherapy traineeship (http://www.ascpfoundation.org/traineeships/train_hiv aids.htm), HIV pharmacy practice specialty residencies, and infectious diseases specialty residencies that include an emphasis on HIV and AIDS.^{243, 263} This is in addition to the valuable contributions made by pharmacists to the literature regarding standards of care for patients with HIV or AIDS.²⁶⁴

Future Directions

To have a meaningful effect on achieving the Healthy People 2010 objectives, pharmacists need to continue to expand a two-pronged attack against HIV and AIDS. First, infectious diseases pharmacists need to continue their specialized work in caring for infected individuals and to publicize this work. Documentation of their innovative efforts in providing care to infected individuals and in preventing spread of HIV can help other pharmacists succeed in similar efforts.

Second, much broader participation by pharmacists is needed to help prevent HIV transmission, by promoting safe-sex practices and encouraging condom use. Despite the success of antiretroviral therapy, prevention is vastly preferable to treatment, prevention is possible, and condoms continue to be underused. Practical educational strategies that can be instituted in many settings are available from Planned Parenthood at <http://www.plannedparenthood.org/education/condomweek.pdf>.

Challenges and Opportunities

The relative lack of public health training in pharmacy schools presents a challenge to expanded professional roles in HIV prevention or similar public health problems. Few role models exist in public health pharmacy, and schools have little expertise or faculty depth in this area. Even for those pharmacists who are heavily involved in innovative care for patients with HIV and who present their findings at professional meetings, most of this work does not culminate in full journal articles. (The same is true for other

health care professionals, it is fair to note.) Lack of publication in peer-reviewed journals decreases the visibility of pharmacy's efforts in this area.

Up-to-date information on HIV therapy, although available on government and other Web sites, may be unwieldy and difficult to download. Concise and current material and free continuing education exists on the Internet, but many pharmacists cannot access the Web at work.²⁶⁵ A lack of privacy for patients in many community pharmacies creates a barrier to caring for patients with HIV. In addition, concerns have arisen regarding the business impact on a pharmacy with a large number of high-risk patients.²⁵⁴ The belief systems of some pharmacists can cause reluctance to promote condom use. There can also be a lack of understanding or acceptance by some members of the public or the profession, resulting in a backlash against practitioners who are active in this area.²⁶⁶ Finally, there are legal barriers for those attempting to reduce the spread of disease among individuals who take intravenous drugs. Lack of clarity in needle and syringe prescription laws creates a diversity of approaches and attitudes among pharmacists toward nonprescription needle and syringe sales.²⁵⁷

Most of the practitioners heavily involved in the care of HIV-infected individuals are in academic or government settings. Extending this practice to more practitioners in community and nonacademic hospital settings is desirable. Further cost-justification efforts are necessary for this to occur.

Finally, minority health professionals are more likely to serve in areas with more under-represented ethnic minorities. Given that many individuals at high risk for HIV are from minority groups, a continuing challenge has been the inability of the profession to train a sufficient number of ethnic minority practitioners. In 2001, for example, underrepresented minorities (African-American, Hispanic, and American Indian) received only 10.1% of the entry-level baccalaureate and doctor of pharmacy degrees in the United States.²⁶⁷ It is thus crucial that schools of pharmacy recruit and graduate a higher number of such individuals.

Recommendations

- Schools of pharmacy need to increase their emphasis on public health and disease prevention.

- Professional pharmacy organizations and schools of pharmacy should encourage practitioners working in HIV clinics to document and publish their efforts in full-length journal articles. Busy practitioners often do not have the time or impetus to publish their contributions, but publication is a highly desirable avenue to promote the profession's contributions to policymakers, other health care professionals, and the general public.
- Professional organizations should encourage economic analyses of the effect of pharmacists on the treatment and prevention of HIV infection.
- Professional pharmacy organizations can provide education about measures to prevent the spread of HIV and other sexually transmitted diseases and about related needle and syringe laws.
- Schools of pharmacy should continue to intensify their efforts to recruit and graduate individuals from underrepresented minorities.

Immunization and Infectious Diseases

The overall goal for this focus area is to prevent disease, disability, and death from infectious diseases, including vaccine-preventable diseases.

Background

Pharmacists have a leadership role and are in an ideal position to advance patient care for each of the objectives of this focus area. Pharmacists serve in an educator, facilitator, and immunizer role in helping to prevent diseases by both universal and targeted vaccination programs, by ensuring vaccination coverage, and by ensuring vaccine safety. Especially through their roles in infection control and antibiotic management programs, pharmacists also assist in preventing disease, disability, and death from infectious diseases.

Pharmacy's Position

The American College of Physicians–American Society of Internal Medicine support the role of pharmacists as an immunization information source, a host of immunization sites, and a provider of immunizations, as allowed by state law.¹ Both APhA and ASHP advocate for the pharmacist's role in immunizations (<http://www.aphanet.org/pharmcare/ImmunizationInformation.htm>),²⁶⁸ as have other pharmacy leaders.^{269, 270}

The APhA pharmacy-based immunization delivery program has trained more than 4000 pharmacists for immunization roles.²⁷¹ As of October 3, 2001, 31 states had granted authority to pharmacists to immunize patients. Position papers by ASHP and the Society of Infectious Diseases Pharmacists have advocated for the pharmacist's role in infectious diseases.^{272–275} The availability of specialists in infectious diseases, and the recognition of infectious diseases as an area of added qualification by the Board of Pharmaceutical Specialties, highlights further the importance of this Healthy People 2010 focus area to pharmacy.

Documented Impact

The epidemiology of people vaccinated by pharmacists has been described previously.²⁷⁶ In general, survey respondents vaccinated by a community pharmacist were satisfied with the experience, would recommend it to others, and considered pharmacists advantageous compared with other vaccine providers based on access, proximity, trust, convenience, and/or cost. Another report describes pharmacists' involvement in and willingness to provide immunization services.²⁷¹ Pharmacists who attended immunization-related educational programs were more willing to provide immunization services. Pharmacists who participated in APhA's immunization certification program reported overall satisfaction with their training, and more than half reported involvement in immunization services.²⁷⁷ These published descriptions of immunization services suggest a marked benefit to the providers and a significant impact on the communities served by the pharmacies. One group of authors proposed a cost-benefit model for a pharmacist-advocated pneumococcal vaccine program that showed it would be 2.5 times more beneficial to a managed care organization than traditional vaccination programs.²⁷⁸ Another group proposed a cost-effectiveness model for a pharmacist-based influenza vaccination program which suggests that advising 100,000 patients for influenza vaccine would avert 139 hospitalizations and 63 deaths, and yield Medicare a savings of \$280,588.²⁷⁹

The role of the pharmacist in promoting optimal antimicrobial use by antibiotic control policies, decision support, provider education, clinical guidelines, audit and feedback, and multifaceted interventions has been described.²⁸⁰ One group described a pharmacist-managed *Helicobacter pylori* clinic,²⁸¹ and other groups

have described pharmacists' involvement in tuberculosis control.^{282, 283} A randomized, prospective study measured patient outcomes after antibiotic therapy intervention by a multidisciplinary consult team that included a pharmacist and demonstrated improved outcomes and cost savings in hospitalized patients receiving intravenous antimicrobials.²⁸⁴ The role of the pharmacist in promoting evidence-based antibiotic use was demonstrated in a randomized trial.²⁸⁵ Improved dosing of the antibiotic and a trend for improved clinical outcomes were demonstrated in patients when guidelines were followed.²⁸⁵ Two other reports describe the positive effect of pharmacists on antibiotic utilization.^{286, 287}

Future Directions

Pharmacists already have exerted a leadership role by promoting and managing immunization programs. The collaboration of APhA and the CDC in establishing a formalized training program can serve as a model for other areas of health promotion and disease prevention. Excellent guidelines for an expanded leadership role for pharmacy have been put forth by APhA (<http://www.aphanet.org/pharmcare/ImmunizationInformation.htm>).

Payment for immunization services is an important consideration, and pharmacists can apply for immunization-provider status from Medicare. Although pharmacists have played a role in infectious diseases and antimicrobial management for many years, few studies have examined the effect of pharmacists on patient outcomes in this area. Such reports are needed to further promote the pharmacist's role in immunization and infectious diseases.

Challenges and Opportunities

Not all states recognize pharmacists as immunizers. Not all pharmacy schools include immunization education and training as part of their curricula. A recent survey of pharmacists who participated in APhA's immunization certification program identified perceived barriers to providing immunization services.^{271, 277} Only 53% of respondents knew whether their states allowed pharmacists to administer immunizations.²⁷¹ Pharmacists rated lack of time, concern for legal liability, and lack of payment as the top three obstacles to the provision of immunization services. Targeted educational programs that provide information on the scope of immunization

practices, liability, payment, and initiation of an immunization service would help address some of these barriers. The role of the pharmacist in infectious diseases and in antimicrobial management is not yet universally recognized by other health care professionals. Efforts to document the positive effect and promote the role of the pharmacists in this area are needed.

Recommendations

- Pharmacy organizations should advocate for legal recognition of pharmacists as immunizers in states where such is lacking.
- Pharmacy organizations should collaborate with each other and the CDC to minimize the perceived barriers associated with pharmacist-provided immunization.
- The American Association of Colleges of Pharmacy and the Accreditation Council for Pharmacy Education should advocate for required education and training in immunization delivery for all pharmacy students.
- Studies that document the contributions of pharmacists as immunizers on patient outcomes should be funded.
- Pharmacists should be made aware of available payment mechanisms for immunization services.
- Pharmacists should be better educated about establishing an immunization service, including the development of a business plan.
- The ACCP should work with the Society of Infectious Diseases Pharmacists to better document the role and value of pharmacists in infection control and antimicrobial management.
- Outcomes studies that document the contributions of pharmacists in infectious diseases and antimicrobial management should be funded.
- Pharmacists who practice in infectious diseases should be encouraged to seek recognition of added qualifications in infectious diseases by the Board of Pharmaceutical Specialties.

Medical Product Safety

The overall goal for this focus area is to ensure the safe and effective use of medical products, including drugs.

Background

A responsibility to ensure drug product safety

has been an important element of pharmacy practice since the birth of the profession. Other health care professions recognize this vital role of the pharmacist.¹

The Institute of Medicine report, *To Err is Human: Building a Safer Health System*, emphasizes the need to address medication errors as one element of patient safety.²⁸⁸ This report, coupled with the General Accounting Office publication, *Adverse Drug Events*,²⁸⁹ focuses attention on the inpatient hospital setting but does not fully address the need for careful interventions to reduce medication errors in outpatient, community-based settings.

Pharmacy's Position

More than 1 billion outpatient visits to clinicians occur each year, half of which result in a new prescription.²⁹⁰ When combined with existing pharmacotherapies, more than 2.7 billion prescriptions are filled annually in the United States. To prevent costly iatrogenic illness, strategies should combine primary care health system interventions and community-based approaches. Because of their positioning throughout the community and within health systems, pharmacists are well placed for a central role in addressing this issue.

Documented Impact and Future Directions

One group reported that drug-related complications occur in 18% of outpatients, with 48% of these seeking medical attention and 5% requiring hospitalization.²⁹¹ Risk factors for medication errors include language barriers, failure to communicate to patients the likely adverse effects of a prescribed drug, and lack of current knowledge of drugs.^{291, 292} Scant attention is paid to the education of all health professionals about medication errors, or effective strategies to reduce them.²⁹² Effective community-based approaches exist. One such example is PHARMAssist, a community-based education program that provides poor, elderly patients with information about drug dosing schedules, adverse effects, and who to contact when prescriptions run out.²⁹³ This program resulted in a 23% reduction in emergency department visits within this fragile population at 6 months and 58% at 1 year.

A critical need exists for an improvement in drug prescribing and use as an integral part of the provision of health care. Because the bulk of previous research on patient safety and medical

errors has been done in the inpatient setting, recent reports from the Institute of Medicine and General Accounting Office are focused on the hospital, with only limited discussion of community-based outpatient settings. Although there are ample opportunities to improve care in these community settings, the task is more difficult because many do not have the organized systems and infrastructure found in large health care systems, staff-model health maintenance organizations, or federal health systems (e.g., Indian Health Service, Department of Defense, and Veterans Affairs facilities).

A recent study of 1116 hospitals across the country noted that medication errors occurred in about 5% of patients admitted each year.²⁹⁴ Medication errors that adversely affected patient care outcomes occurred in 0.25% of patients admitted to those hospitals. Factors associated with increased medication errors included a lack of pharmacy teaching affiliation, having centralized rather than decentralized pharmacists, hospital mortality rate, and total cost of care/occupied bed/year. One of the most effective ways to prevent or reduce medication errors is the presence of decentralized pharmacists in patient care areas.

When a pharmacist was included on patient care rounds in the intensive care unit of a large, urban teaching hospital, preventable adverse drug events decreased by 66%. This yielded projected annual savings of \$270,000. During a 6-month period, pharmacists intervened about 400 times on behalf of patient safety, with 366 of those occasions relating to medication errors. Errors included incomplete orders, incorrect dosages, suboptimal drug choices, and prescription duplication. Health care professionals, including nurses, responded positively to the pharmacists' presence on rounds. Physicians accepted 99% of the pharmacists' recommendations for intervention.⁸

Including pharmacists in initiatives to enhance systems of care has resulted in fewer medication errors and improved the quality of care in both primary care²⁹⁵⁻²⁹⁷ and institutional settings.²⁹⁸⁻³⁰¹ For example, in a study of newly anticoagulated ambulatory patients treated with usual medical care compared with those treated in a pharmacist-managed anticoagulation clinic, the authors found that patients treated in the pharmacist-managed clinic had better anticoagulation control, fewer bleeding and thrombotic complications, fewer hospitalizations and emergency department visits, and lower health

care costs. Annual health care costs for patients managed in the pharmacist clinic were reduced by \$162,058/100 patients.²³³ Studies performed in other ambulatory practice settings in various populations (e.g., diabetes, asthma, polypharmacy, immunization) have demonstrated similar reductions in adverse drug events with concurrent cost savings.³⁰²⁻³⁰⁴ Overall, initiatives such as those described above have demonstrated improved drug use education and infrastructure, especially in underserved areas; provision of culturally appropriate drug use services; and an increase in pharmacy surveillance activities.

Challenges and Opportunities

A systems approach to identifying and addressing the issue of medical product safety is needed.³⁰⁵ A current challenge to achieving objective 17-2 (Table 2) is that access to comprehensive patient health-data systems is less than optimal, or that such systems do not exist in many health care settings.³⁰⁶

Recommendations

- An integrated patient health-data system that both includes and connects community and institutional health care systems (e.g., between community pharmacies and institutional pharmacy departments) should be developed. Efforts to address this issue will need to target at-risk populations, improve care processes, and evaluate outcomes. These efforts will facilitate continuity of care and minimize problems related to medical products. Specific examples include applying information technology in health care system practice settings to improve patient care and reduce errors (e.g., computerized prescribing and automated pharmacotherapy monitoring systems, patient and provider reminders, computerized medical records, protocols for routine follow-up and standing order systems); using clinical pharmacists to both educate patients and provide advice about prescription choices, adverse drug events, and drug interactions (i.e., “closing the loop” from the prescriber to patient to pharmacist to prescriber); and establishing coalitions of collaborative primary care practitioners, hospitalist physicians, and pharmacists to share patient information better, prevent unanticipated drug-drug interactions, and monitor the actual use of a patient’s

pharmacotherapies, without inducing any risk to those practitioners who report adverse drug events.

- The epidemiology of medication errors in both inpatient and outpatient settings should be studied and the efficacy of interventions in both settings should be rigorously tested to reduce errors.
- Curricula and competency requirements regarding medication errors and patient safety should be incorporated throughout the health professions education system. Curricula in the entry-level programs should include information about known risk factors for medication errors and effective interventions. Health professionals, especially at the resident level, should develop competencies in interdisciplinary approaches to reducing medication errors. Core curricular components and competencies such as those recommended by the Joint Commission for Accreditation of Health Care Organizations should be used as a starting point for curriculum development. Pharmacists can take a leading role in its development.
- The United States Food and Drug Administration’s (FDA) ongoing development of a patient-centered adverse drug event surveillance system empowers patients or their caregivers to be more involved in their care. This system is designed to target at-risk populations and includes a toll-free reporting number and Internet reporting of suspected adverse drug events or medication errors. It can serve to educate both clinicians and patients about medical errors and adverse drug events but must include a multicultural patient education campaign. Pharmacists can and should take an active role in both the development and use of such a system.

Mental Health and Mental Disorders

The overall goal for this focus area is to improve mental health and ensure access to appropriate, quality mental health services.

Background

The specific objectives that provide an opportunity for an expanded leadership role by pharmacists are objectives 18-6, 18-7, 18-9, and 18-10 (Table 2). Because pharmacotherapy plays an important role in the treatment of mental disorders, pharmacists can play an important role in meeting these Healthy People 2010 objectives.

Pharmacy's Position

Pharmacists with specialized training in psychiatry can increase the number of persons who receive mental health screening and assessment, increase the proportion of children with mental health problems who receive treatment, increase the proportion of adults with mental disorders who receive treatment, and increase the proportion of persons with co-occurring substance abuse and mental disorders who receive treatment for both disorders. At the time of this writing, 387 psychiatric pharmacists were certified as such by the Board of Pharmaceutical Specialties. The ASHP also has advocated a role for pharmacists in recognizing and treating depression.³⁰⁷

Documented Impact

One group of authors reported on pharmacist-implemented pharmaceutical care plans for antipsychotic-induced movement disorders.³⁰⁸ The pharmacist's role in the treatment of patients receiving injectable long-acting fluphenazine also has been described.³⁰⁹ Other authors have described the contributions of pharmacists to the care of patients with psychiatric disorders, especially in hospital settings.³¹⁰⁻³¹⁸ In these reports, pharmacists have provided information about drug interactions, pharmacokinetics, and alternative treatment options; participated in collaborative care agreements in which they were involved with assessment, development, and implementation of treatment plans, and education of patients with psychiatric disorders; monitored response to drugs, adjusted drug therapy, and ordered laboratory tests under protocol.

Several articles demonstrate the effect of clinical pharmacists on the outcomes of patients with mental disorders. Most of these are retrospective study designs with historic controls.^{300, 319-325} All report favorable findings, especially with regard to appropriateness of psychotropic prescribing. In one of these reports, the results of a pre- and postintervention study demonstrated that the provision of clinical pharmacy services to inpatients in an acute care psychiatric facility was associated with improvements in rating-scale scores for clinical response and drug-induced extrapyramidal symptoms.³⁰⁰ In a study of inpatients with psychiatric disorders, the authors showed that pharmacist prescribing compared favorably with that of physicians for anticholinergics but was

significantly better for antipsychotics and antidepressants.³²⁴ Another group of authors describe the effect on outpatients with psychiatric disorders of pharmacists' case management services that included patient education, drug therapy monitoring and adjustment, or drug prescribing under protocol.³²⁵ Greater improvement in overall health and a trend toward greater patient satisfaction were demonstrated.

A few studies have evaluated the effect of pharmacists on depression management in primary care settings.³²⁶⁻³²⁹ In one study, the authors observed increased drug adherence rates, enhanced patient satisfaction, and a decrease in primary care visits when pharmacists served as care managers in a depression clinic.³²⁷

Future Directions

Increased and improved documentation of the contributions of pharmacists in the area of mental health is needed. Action on the specific recommendations proposed would help to expand the pharmacist's role in improving mental health and ensuring access to appropriate quality mental health services. Opportunities exist for pharmacists to affect the outcomes of psychiatric disorders, especially by involvement in population-based research and by conducting health economic and epidemiologic investigations.^{330, 331} One area that has not been well developed is pharmacist involvement in community mental health. Community pharmacists could promote awareness of psychiatric disorders, provide education on treatment options, and affect patient outcomes positively through collaborative care agreements.

Challenges and Opportunities, and Recommendations

- Pharmacy should partner with mental health organizations, including the National Institute of Mental Health, to increase the collaborative role of the pharmacist in caring for patients with mental disorders.
- Pharmacy should seek funding from the National Institute of Mental Health and other agencies to support research that studies the effect of clinical pharmacists' services and care on the outcomes of patients with psychiatric disorders.
- Pharmacists who practice in a mental health pharmacy should be made aware of and encouraged to pursue board certification

through the Board of Pharmaceutical Specialties.

- The value of such board certification to practitioners and patients should be evaluated.

Respiratory Diseases

The overall goal for this focus area is to promote respiratory health through better prevention, detection, treatment, and education efforts.

Background

Most commonly, chronic obstructive pulmonary disease (COPD) occurs among older people with a history of smoking. In fact, an estimated 10% of patients aged 65 years or older have COPD, and 80–90% of COPD cases are attributed to smoking. In Healthy People 2010, two objectives have been developed to improve quality of life and reduce health disparities due to this disease (objectives 24-9 and 24-10, Table 2).

Asthma is largely managed with pharmacotherapy, and the proper use of prescribed drugs is key to optimal treatment of both asthma and COPD. Inadequate metered-dose inhaler (MDI) technique is a common occurrence, which can be noted in up to 22% of patients with asthma. In addition, 16.4% of patients take short-acting β_2 -agonists excessively, and 21% of patients with asthma do not take an inhaled corticosteroid.³³² Patients who do not take their drugs correctly are not likely to have adequate control of their asthmatic and COPD symptoms, reducing their quality of life through repeated emergency department visits, hospital admissions, and chronic underlying wheezing. Unless the technique for drug use is properly assessed, the reason for suboptimal patient response to prescribed drugs may be unrecognized and health care professionals may be tempted to prescribe unnecessary drugs, resulting in polypharmacy. The pharmacist's role is established in this arena. Many pharmacists are taking a leadership role and have reported their positive outcomes and challenges in managing patients with chronic respiratory diseases.

In the United States, obstructive sleep apnea (OSA) has been estimated to occur in more than 18 million individuals. Obstructive sleep apnea severely disrupts the normal sleeping pattern, resulting in diminished productivity, excessive daytime drowsiness, and reduced alertness. As a result, patients with OSA are at increased risk for

cardiovascular death, exacerbation of other respiratory disease(s), vehicular crashes, sexual dysfunction, and difficulties with interpersonal relationships. Two objectives related to OSA have been included in this focus area (objectives 24-11 and 24-12, Table 2), but there are no studies that describe the pharmacists' role in caring for these patients.

Pharmacy's Position

Pharmacists are appropriately positioned and trained and are well suited to address Healthy People 2010 objectives related to respiratory diseases.³³³ Once patients obtain the maximum benefit from their respiratory drugs, they are less likely to be admitted to the hospital and thus have fewer absences from school or work. Patients with asthma will be better able to participate in physical activities and have an overall improved quality of life. The National Asthma Education Program recommends that pharmacists instruct patients on inhaler use with each new prescription for an inhaled β -agonist.³³⁴ Likewise, the National Heart, Lung, and Blood Institute advocates that pharmacists be part of the partnership with other health care professionals for the provision of care to patients with asthma.³³⁵

Many community and hospital pharmacy practices are initiating programs to better target patients with asthma who are poorly controlled and to counsel patients on how to use their drugs.³³⁶ Studies have shown that with pharmacist counseling, hospitalizations and emergency department visits will be reduced, and patients benefit from an overall satisfaction with their asthma management. As with patients with asthma, many pharmacists are positioned to provide care to patients with COPD and to work toward Healthy People 2010 objectives. Pharmacists who provide counseling on smoking cessation can significantly affect Healthy People 2010 objectives related to COPD (see Tobacco Use section).

Pharmacists can recognize drugs and drug regimens that may interfere with normal sleep. Pharmacists frequently take drug histories and discuss with patients the adverse effects such as drowsiness, daytime sleepiness, or insomnia. Through good patient counseling, pharmacists should be able to identify patients with signs and symptoms of OSA and facilitate appropriate medical evaluation. However, adequate education and training must be provided to

current and future pharmacists if they are to make a significant contribution toward Healthy People 2010 objectives related to OSA. Pharmacy school curricula and textbooks devote little, if any, attention to sleep disorder medicine. An opportunity exists to expand OSA awareness and teaching. Pharmacists who currently provide services for cardiology, neurology, and respiratory diseases should consider expanding their scope to include sleep-disordered breathing. In this way, pharmacists may be able to contribute to Healthy People 2010 objectives for OSA.

Documented Impact

Deaths from Asthma

Some evidence suggests that pharmacists in Australia may have contributed to a 24% reduction in asthma-related deaths during the late 1980s.³³⁷

Hospitalizations for Asthma

Pharmacists' services have been shown to decrease the frequency of hospitalizations from asthma.^{303, 338-340} None of 40 patients who received counseling from pharmacists about their asthma drugs required hospitalization during a 12-month study period, compared with 8 of 37 patients in a control group ($p=0.002$).³³⁹ A Danish study assessed 500 patients during a 12-month period to evaluate the effect of a pharmacist-led therapeutics outcomes monitoring (TOM) program. There were 4 hospital admissions in the TOM group compared with 11 in the control group (statistical significance not measured).³⁴⁰ Finally, one study showed that pharmacists may contribute to a 77% reduction in hospitalizations and 25% reduction in urgent care center visits.³⁰³

Hospital Emergency Department Visits for Asthma

Counseling of patients with asthma by pharmacists has dramatically reduced asthma-related visits to the emergency department.^{34, 303, 338, 341-343} Six months after a comprehensive patient education program was implemented in a sample of 25 adult patients with asthma, the number of emergency department visits was reduced from 92 to 47. This training program provided education about asthma and proper use of asthma drugs, regular telephone contact between the pharmacist and patient, and an open-door clinic policy.³⁴ Another study showed a 78% reduction in emergency department

visits.³⁰³ In another study, pharmacist counseling resulted in a significant improvement in the proper use of MDIs, a 66.6% reduction in emergency department visits, and a significant cost savings.³³⁸ However, not all studies have substantiated these results. Emergency department visits did not change between intervention and control groups for the pharmacist-led TOM program cited above, with each group reporting four visits during the 12-month study period.³⁴⁰

Initial noncompliance with antiasthmatic drugs is likely to lead to recurrent admissions to the emergency department. However, in one study, the pharmacist had a negligible effect on the number of unclaimed discharge prescriptions.³⁴³ Nonetheless, more patients in the control group (no pharmacist intervention) returned to the emergency department with asthma exacerbations. This led the investigators to suggest that it may be more beneficial for the pharmacist to intervene earlier during the discharge prescription process.

School or Work Days Lost

A study using an intervention group receiving pharmacist counseling compared with a control group was unable to show a significant difference in days missed from school or work between the groups.³³⁹

Patient Education

Pharmacists are interested in counseling patients about their asthma, beyond simply demonstrating the proper use of an MDI.^{342, 344-351} Pharmacists have created counseling areas that incorporate drug education, compliance measurement with improvement techniques, and inhaler demonstration with assessment.³⁵² In addition, patients who received counseling from a pharmacist demonstrated a positive correlation between their knowledge of and attitudes toward antiasthmatic drugs at 12 months ($p=0.04$). Patients' change in behavior persisted throughout the 1-year follow-up period.^{339, 352-355}

Counseling provides patients with knowledge about their disease, pharmacotherapy, and self-management, which leads to significant improvements in evening peak flow rates and self-efficacy.³⁵⁶ Proper use of MDIs increased significantly during a 1-year period of pharmacist counseling.³³⁸ Patients with asthma reported significant decreases in the frequency of daytime asthma symptoms, nocturnal symptoms, and use of short-acting β_2 -agonists. At the same time,

patients reported an increased use of their preventive drugs.³³²

Pharmacists in Arkansas found telepharmacy counseling to be useful for teaching optimal MDI technique. Patient satisfaction with this method was significantly greater than when they were simply provided with the written instructions that accompany a MDI package insert ($p < 0.001$).³⁵⁷ Another study suggests using a patient training video to provide counseling to a large number of patients when adequate staffing for this service is not feasible.^{358, 359} Not surprisingly, pharmacists who counseled their patients with asthma face-to-face were able to teach proper MDI technique more effectively, when compared with just providing written instructions.³⁶⁰ Pharmacists are even training primary schoolteachers to develop their knowledge of the conditions affecting many of their students.³⁶¹

Appropriate Asthma Care

Pharmacists' interventions with patients who had asthma that was poorly controlled reduced the number of patients treated with oral steroids, lessened the number who had peak expiratory flow rates below 85%, and yielded a net improvement with at least one of their asthma symptom indicators in 79% of patients.³⁶² Patients experienced a decrease in the severity of their asthma symptoms at the conclusion of this 12-month study compared with the preceding 12 months when pharmacists did not provide any active interventions. Pharmacist intervention can have a positive effect on several clinical outcomes in patients with asthma, including peak expiratory flow rates, changes in daily asthma drugs, and use of oral steroids.³⁶² Thankfully, pharmacist-initiated interventions in care are accepted at a high rate. In one study, up to 90% of interventions were accepted by the patients' primary care physicians.³⁶³

After receiving appropriate counseling by pharmacists, patients had a 12% reduction in the use of their β_2 -agonists during a 1-year period compared with only a 1% reduction in the control group. Inhaled corticosteroid use increased by 50% in the pharmacist-counseled group compared with 9% in the control group.³⁶⁴

A TOM program in Denmark was established by community pharmacists. After a 12-month randomization, patients in the TOM group had 793 days of sickness compared with 1249 days in the control group, a statistically significant difference. Parallel to this finding, patients in the

TOM group reported a significantly higher health-related quality of life.³⁴⁰

Pharmacists studying their care of patients with asthma in South Africa found that patients who assessed their asthma severity by using a visual analog scale (VAS) were more likely to underestimate the severity of their condition than did those patients who regularly used a peak expiratory flow rate self-monitoring system. As a result, patients in the VAS group were more likely to use their drugs inappropriately.³⁶⁵

Chronic Obstructive Pulmonary Disease

Pharmacists have contributed to a reduction in the proportion of adults whose activity is limited due to chronic lung and breathing problems, through their patient education and disease management programs. Although studies to evaluate these programs have been presented in abstract form only, it appears that pharmacists have improved quality of life for patients with COPD. At a minimum, it is highly likely that many pharmacists are providing education about proper inhaler technique to patients with COPD.³⁶⁶

Future Directions

Increased and improved documentation of the contributions of pharmacists in the area of respiratory disorders is needed. Also, additional training and credentialing will help pharmacists in all practice settings meet the needs of patients with lung diseases. The APhA has established an asthma disease management credentialing program. It consists of a study guide for pharmacists preparing for the asthma disease state management examination offered by the National Institute for Standards in Pharmacist Credentialing. The program provides a comprehensive review of the pathophysiology, assessment, diagnosis, and treatment of asthma.³⁶⁷

Challenges and Opportunities

Not all pharmacists provide counseling to meet patients' needs and expectations, which may be due in part to a lack of confidence in managing patients with respiratory disease.³⁶⁸⁻³⁷⁰ Other pharmacists may be frustrated because third-party payers do not usually pay for the provision of in-depth counseling sessions.³⁶⁶ Regional pockets of patient dissatisfaction may be present. One analysis in New York City found that patients' perceptions of counseling in the

community pharmacy setting about their asthma drugs was low and did not adequately address their education needs.³³

In an effort to overcome the difficulties associated with establishing a counseling program for patients with respiratory diseases, several articles have described the success of pharmacists in this focus area.^{303, 359, 371–380} Increased public awareness of pharmacists' capabilities and a more proactive approach to the provision of cognitive services are needed.³⁸¹

Recommendations

- Pharmacists should recognize the opportunity for asthma and COPD counseling services at their practice sites and take action to fill the void in patient education and patient care.
- Pharmacists should seek the advice of other health care professionals in initiating and coordinating counseling and other patient care services.
- Pharmacists should work collaboratively with other health care professionals to promote a successful interdisciplinary practice.^{375, 382–385}
- Pharmacists should be aware of and seek credentialing in asthma-related pharmaceutical care to ensure the public and others of their expertise.
- Pharmacists and pharmacy organizations should promote the importance of the pharmacist's role in providing counseling to patients with COPD and asthma.
- Professional pharmacy organizations should continue to provide positive public relations messages to the lay public and other health care professionals.
- Professional pharmacy organizations should support and participate in the development of asthma surveillance programs, similar to the Chicago Asthma Surveillance Initiative.³⁸⁶

Tobacco Use

The overall goal for this focus area is to reduce illness, disability, and death related to tobacco use and exposure to secondhand smoke.

Background

There are 21 specific objectives related to the Healthy People 2010 goal pertaining to tobacco use, and these are grouped into four domains: tobacco use in population groups, cessation and

treatment, exposure to secondhand smoke, and social and environmental changes (Table 2). This report focuses primarily on the participation of pharmacists in tobacco use cessation and treatment.

Pharmacy's Position

Successful achievement of Healthy People 2010 objectives will depend, in part, on a multidisciplinary effort focused on patient education, behavior modification, and frequent reinforcement. The tremendous opportunity for pharmacist-patient communication, along with the accessibility of nonprescription smoking-cessation products (e.g., gums and transdermal patches) in community pharmacies, place the profession in a strategic position to be a key contributor. Given this environment, pharmacists can address disparities such as the higher prevalence of tobacco use among certain age, sex, and ethnic subgroups by focusing and tailoring efforts toward these groups.

Documented Impact

Numerous articles have addressed the feasibility and effectiveness of pharmacist-centered activities related to smoking cessation. A recent review of community pharmacy contributions to smoking cessation concluded that the most successful programs were those that included personalized advice and assistance, repeated in different forms over the longest possible period of time.³⁸⁷ Successful development, implementation, and outcomes of this approach in chain pharmacies have been reported.^{388, 389} A comprehensive smoking-cessation training program was developed and used to train pharmacists at several chain pharmacies in Virginia. Subsequently, pharmacist-managed smoking-cessation clinics were established at these sites, offering semiprivate counseling for patients who were interested in quitting. These pharmacists also gathered data on patient satisfaction. Of the 48 patients included in the analysis, cigarette smoking abstinence rates at 1, 3, 6, and 12 months were 43.8%, 31.3%, 25.0%, and 25.0%, respectively. Furthermore, patients expressed satisfaction with the pharmacist counselors and the program.

The effectiveness of a pharmacist-based smoking-cessation program and its effect on quality of life also have been evaluated in a single-group, prospective, open-label trial.³⁹⁰ This program consisted of nicotine replacement

therapy (gum or transdermal patch) and 1-hour, pharmacist-facilitated counseling and behavior modification sessions offered to 31 self-referred patients during 12 weeks. Abstinence rates at 3 and 6 months were 42% and 26%, respectively. During the 3-month program, health-related quality of life (vitality, mental health, and self-control) significantly improved for patients who had quit smoking. Other researchers examined the feasibility of pharmacists working with physicians to deliver disease management services, including smoking-cessation interventions, to patients with ischemic heart disease.³⁹¹ Pharmacists and physicians involved in this initiative reported high levels of satisfaction with respect to both the clinical outcomes of patients and professional collaboration.

Pharmacist participation and the use of bupropion in outpatient smoking-cessation programs have been described.^{27, 392} One group reported the outcomes of patients referred to a pharmacist-managed outpatient smoking-cessation program by primary care physicians.²⁷ All patients received pharmacotherapy, behavioral counseling by a clinical pharmacist, and educational materials on smoking cessation. Abstinence rates were 28.2% and 25.4% at 8 weeks and 6 months, respectively.

Another group evaluated the effectiveness of a Pharmacists Educating Patients Program in which pharmacists were provided with smoking-cessation consultation guidelines.³⁹³ This study involved more than 6500 pharmacies and included 40,220 patients receiving nicotine transdermal therapy. Patients who had joined a comprehensive smoking-cessation program and were counseled by a pharmacist had a self-reported smoking-cessation rate of 45% at 10 months after treatment compared with a rate of 37% after 5 weeks for patients who received only counseling by a pharmacist. Based on patient survey results, these authors concluded that intense counseling and support by pharmacists for patients receiving nicotine transdermal therapy can improve smoking-cessation rates. Similar results were found in a study of individuals who used a patch. More frequent contact with physicians and/or pharmacists was associated with higher quit rates ($p < 0.005$).³⁹⁴

A multidisciplinary smoking-cessation program including nurses, pharmacists, and physicians in large health maintenance organizations in the Pacific Northwest has been described.^{395, 396} Interventions in this program included assessment of smoking status, behavioral modification, and

nicotine replacement therapy. Pharmacists were trained to use a protocol for promoting smoking cessation, and continuing education sessions were provided. Responsibilities of pharmacists included determining nicotine replacement dosages, monitoring efficacy and tolerability to therapy, and providing patient education. The rates of long-term abstinence achieved with these approaches were similar to reported rates for community-based group smoking-cessation programs.

Additional published reports describe pharmacy practice models for smoking-cessation programs that have been implemented with success.^{397, 398} One group studied the effect of a stage-of-change model used by pharmacists and pharmacy technicians in the United Kingdom.³⁹⁸ When compared with a control group, patients who participated with pharmacists in this model of care were more likely to engage in discussions with their pharmacists, reported higher satisfaction with their discussions, and experienced a trend toward higher self-reported smoking-cessation rates.

Other researchers evaluated a model of care described as the Pharmacists Action on Smoking Program.³⁹⁹ This approach was developed in the United Kingdom for community pharmacists. The model involves a written contract between the patient and pharmacist and a series of counseling sessions over a 6-month period. Cost/life-year saved associated with the program was similar to that of other disease management interventions such as hypertension or hyperlipidemia screening. The authors concluded that this smoking-cessation program was a cost-effective intervention in the community pharmacy setting and was worthy of payment.

Additional research has been conducted to estimate the economic feasibility of pharmacist involvement in smoking cessation in the form of cost-benefit analysis from an employer's perspective. The authors of one report determined that an employer would receive the greatest net benefit from a formal program involving the use of nicotine patches with smoking-cessation consultation from a pharmacist.⁴⁰⁰ Furthermore, they determined that pharmacists could charge a consultation fee of up to \$109/patient and the program would remain cost-effective.

Future Directions

A substantial volume and variety of work related to this topic have been conducted in the United States and other countries. This work has

focused on effectiveness, economics, alternative models, and challenges associated with pharmacists' involvement in smoking-cessation programs. Adequate data and descriptive reports are available in the literature to conclude that independent or collaborative pharmacist participation in smoking-cessation programs is feasible, effective, and economic. Other advantages include improved satisfaction for participating pharmacists, collaborating health care professionals, and patients. To optimize the role pharmacists will play in achieving Healthy People 2010 objectives, practice models such as those described above should be evaluated and implemented on a larger and more consistent scale. Data also exist to support pharmacists charging a consultation fee as part of the performance of these activities. Standardization of a billing component would provide a financial incentive to pharmacy retail organizations and make wide-scale implementation of such programs more feasible.

Successful efforts by pharmacists should involve implementation of five key components of cessation counseling: asking about tobacco use, advising tobacco users to quit, assessing readiness to quit, assisting with quitting, and arranging follow-up care (the five "As").⁴⁰¹ Contemporary treatment for tobacco cessation, as recommended in this practice guideline, involves the use of pharmacotherapy in conjunction with behavioral counseling. Currently, five pharmaceutical preparations have received FDA approval for smoking cessation: nicotine gum, transdermal nicotine patch, nicotine nasal spray, nicotine inhaler, and bupropion slow-release tablets. Given that each of these products is available almost exclusively through pharmacies, the pharmacist is well positioned to assist patients with quitting and, in fact, might be the only health care provider able to intervene with patients who choose to use nonprescription nicotine replacement therapy as an aid for cessation. Importantly, pharmacists can advise patients on the proper use of these agents.

Challenges and Opportunities

Challenges to pharmacist involvement in smoking-cessation programs include inadequate training for pharmacists, lack of pharmacist time for counseling in the retail setting, lack of pharmacy practice models, poorly defined payment procedures, limited information documenting the cost-benefits of the activity, and

a need to increase public awareness of the pharmacist as a resource for smoking-cessation counseling. Another issue potentially inhibiting expansion of the pharmacist's role in smoking cessation is the widespread sale of tobacco products through retail pharmacy businesses.

The issue of tobacco-cessation training for pharmacists has been addressed. Providing pharmacists with specialized tobacco-cessation counseling training leads to significant increases in counseling activities and improves interactions with patients.^{398, 402} Patients do not typically perceive the pharmacist as a resource for tobacco-cessation assistance. However, patients who have been recipients of pharmacist-facilitated cessation services view the experience positively.^{393, 398} Specific elements of required training may include development of credibility with patients, neurochemistry of addictive disorders, nondrug alternatives, nicotine cessation, and philosophies of behavior modification.⁴⁰³

Recommendations

- Efforts that support the dissemination of adequate training and competency assessment for pharmacists in conjunction with the establishment of feasible payment strategies should be pursued. These will be instrumental to extending the level of pharmacist involvement in these types of programs.
- Pharmacists' activities in this area should be better promoted by pharmacy groups. Wide-scale uptake of pharmacist-focused tobacco-cessation and treatment programs among large pharmacy retail organizations and other community pharmacies, and the associated public exposure, should further promote such efforts as core pharmacy services. This, in turn, will further pharmacy's role in meeting the specific Healthy People 2010 objectives for tobacco cessation.
- Resources and programs pertaining to patient and provider education should be developed to guide pharmacists in these efforts and ultimately in helping to achieve these objectives of Healthy People 2010. Some educational resources are available through several health care organizations (e.g., American College of Chest Physicians, American Lung Association).

Discussion

Healthy People 2010 is a landmark document that focuses on population health improvement

through health promotion, disease prevention, and reduction in health disparities. Strategies to reduce health disparities among racial and ethnic minority communities are a great priority. Many of these efforts focus on patient education and improved access to primary care services. In some cases, income, age, race, and sex are secondary to education as the most critical factors influencing health outcomes.

The Health Resources and Services Administration, an agency of the DHHS, has been working to make quality health care available to low-income, uninsured, and isolated individuals and families in underserved communities. Also, the lack of health insurance in America leads to delayed diagnoses, life-threatening complications, and premature deaths because most do not seek health care until an illness becomes too serious to ignore. It is interesting that, as health care costs continue to increase rapidly, the fastest rising component continues to be the cost of pharmaceuticals.

A number of challenges will undoubtedly await health care providers and patients on the road to achieving the stated goals and objectives of Healthy People 2010. These include but are not limited to deficits in education and training, limitations in access (to pharmacists for counseling, to other professionals, to medical records, to insurance, to health services, etc.), inadequate reimbursement for services, lag in information technology, budgetary constraints, fragmentation of health resources, poor coordination across health care settings, limited manpower and resources, increased health care demands (e.g., growing long-term care needs, aging population), poor coordination of health care services, focus on specialization at the expense of primary and preventive care services, and growing demands for more evidence-based medical practices.

Pharmacists can play an active role in helping to achieve the objectives of the Healthy People 2010 initiatives. These roles can be in the form of advocacy, teaching, conducting research, and/or serving as health care providers. Pharmacists must assume more of a leadership role in educating the public and providing direct patient care, especially for underprivileged and underserved communities. Moreover, pharmacists must be leaders in advocacy campaigns to bring critical health resources where they are needed most and to bridge the gaps in areas with the greatest health disparities. Even in areas where they may have a limited role by virtue of their

education and training, pharmacists can nonetheless be contributors as models of health and good citizenship in their own communities.

Healthy People 2010 established the objectives to improve the health of the American population. Many individuals and organizations were involved in the development of these objectives. Regrettably, the profession of pharmacy or care provided by pharmacists was seldom mentioned in the document. It is unclear where pharmacists had direct responsibility for crafting individual sections of the document or had a voice in its overall construction. The ACCP and several other professional pharmacy organizations participated in the Healthy People Consortium, an alliance of more than 400 organizations supporting the goals of Healthy People 2010. However, it appears that pharmacists were largely ignored from the working groups that developed the specific objectives for the 28 focus areas.

We believe that pharmacists must be more involved in the development of national health goals to ensure the optimal use of drugs. Pharmacists must campaign for improved representation on state and federal public health-related panels, including coordinating committees of future Healthy People programs. More visibility for pharmacists will not only help the pharmacy profession, but also undoubtedly improve interactions between pharmacists and the general public. National pharmacy groups such as ACCP are encouraged to join the Healthy People organization of Partners for Prevention. Those organizations belonging to Partners for Prevention are able to recommend individuals to participate in the development of national health-related initiatives.

This White Paper has focused on pharmacists' activities that reflect Healthy People 2010 goals and objectives with a population-based approach. Some focus areas of Healthy People 2010 appear to be deserving of a higher ranking in terms of the potential for pharmacy involvement. However, when the specific objectives in such focus areas were examined carefully, they were determined to be areas in which pharmacists are not particularly active. For example, although there is a critical mass of pharmacists involved in oncology practice as evidenced by board certification in this area, the objectives in the cancer focus area do not emphasize treatment. Instead, the objectives largely identified the significant challenges for the country in prevention of cancer in the community. Pharmacists are involved in some cancer

prevention activities, such as use of sunscreens or counseling patients to participate in screening programs, but this is not reflective of general or highly evolved practices of pharmacists specializing in oncology practice. Although this report does not provide an exhaustive review of the literature of pharmacy practice, the articles cited clearly identify where pharmacists can and do have a direct impact and responsibility for improving health outcomes that address several specific Healthy People 2010 objectives.

Overall, there were three recurring themes in the recommendations for many of the focus areas addressed in this White Paper that will serve as a call to action for the nation's pharmacists. The first is the need for political advocacy especially where information is available that supports the role of pharmacists in achieving the Healthy People 2010 goals and objectives; the second is the need for continued research in areas that lack multicenter, well-controlled studies; and the third theme is the need for education and training in clinical services such as disease state management for all pharmacists.

Political Advocacy

Where published data from well-designed studies of collaborative practice between pharmacists and physicians show clear benefits for patients (e.g., heart disease, stroke, immunizations, family planning), actions from policymakers, pharmacists, and organizations are required. Public policy must be shaped to allow for the development of cost-effective pharmacist-provided services throughout the United States, rather than in a few pockets of excellence. Third-party reimbursement, and specifically Medicare recognition of pharmacists as providers, is a major need. At the writing of this White Paper, a bill was in Congress that would recognize pharmacists as providers of health care services. Once this bill is enacted, a major barrier for pharmacist-provided clinical services will be overcome. Other third-party payers are likely to follow the lead of the federal government as this becomes a recognized standard of care. Community coalitions, employers, third-party payers, and other stakeholders should be made aware of the superior, yet cost-effective, patient outcomes associated with pharmacist-provided care so that they can begin to demand access to these clinical services and hasten this change. Enlisting patient advocacy groups like the American Association of Retired People to support the profession's

advancement into this arena would bring more attention to the need for this action.

All states must incorporate collaborative drug therapy management as a part of their pharmacy practice acts. Regulations for this practice must be streamlined, made more consistent, and adopted throughout the country. Two ACCP position statements address the history and evolution of collaborative drug therapy management by pharmacists.^{404, 405} The ACCP advocates further expansion of collaborative practice by qualified pharmacists.¹³ The National Association of Boards of Pharmacy has included collaborative practice regulations in its model pharmacy practice act, which states should be encouraged to adopt into their own laws and regulations. Standardization of the regulations would strengthen the pharmacist's ability to participate in collaborative practice throughout the country.

Continued Research

Although several areas noted in this paper have clearly documented the improved outcomes seen with pharmacist-provided services, there is a need for continued research in other areas. We found an abundance of citations in the process of identifying and evaluating the literature to provide the foundation for this White Paper. However, most of these were abstracts of papers presented at meetings, which identify pockets of excellence but provide limited data. Also, most abstracts were from single sites and may not be generalizable to other practice settings. Typically, published studies were not outcome-focused, nor were they published in journals likely to be reviewed by those outside pharmacy circles. The profession must continue to publish meaningful data in high-quality, widely read journals. Pharmacists who have presented abstracts at meetings must be encouraged to publish their information in peer-reviewed journals. It is important to note that health policies are developed based on sound evidence, and pharmacy advocacy efforts must be communicated clearly and in a compelling manner.

Multicenter, outcome-focused trials must be conducted to provide the foundation needed to push for optimal drug therapy in the care of patients. Multicenter outcome studies in areas lacking this level of evidence should be federally funded (e.g., Agency for Healthcare Research and Quality). Pharmacists have traditionally not participated as investigators in these types of trials. We must support the independent pharmacist

investigator in developing networks of pharmacy sites conducive to outcomes and health services research. Pharmacists should be mentored in writing grants for these types of studies.

Improved Education and Training

Finally, we call for education and training of all pharmacists to provide clinical services in areas appropriate to their practice settings. Colleges of pharmacy must incorporate disease state management into the curricula, and this must become a core part of the training of pharmacists, as is pharmacology and therapeutics. Chain pharmacies, managed care organizations, hospitals, and other large pharmacist employers should demand this level of expertise and experience for their employees. As these clinical services are approved for reimbursement, the majority of pharmacists must have the skills to provide them.

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