

KEY TERMS

adherence
ambulatory care
collaborative practice
evidence-based medicine (EBM)
health literacy
medication reconciliation
medication therapy management (MTM)
OBRA '90
polypharmacy
primary care

Approach to the Patient and Patient-Centered Care Process

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LEARNING OBJECTIVES

After reading this chapter, the reader should be able to:

1. Describe the scope of ambulatory care practice.
2. Give examples of the pharmacist's roles and responsibilities in providing pharmaceutical care.
3. Describe the elements necessary for applying evidence-based medicine.
4. Identify interpersonal characteristics that embody professionalism.
5. Describe the problems arising from drug therapy management used in the treatment of chronic diseases.
6. Describe practice settings in which ambulatory pharmacists practice.
7. Identify regulations impacting the legal responsibilities of pharmacists providing pharmaceutical care.
8. Compare and contrast traditional pharmacy practice models based on a medication-dispensing role and contemporary practice models.
9. Describe specialization of skills to meet the needs of special populations.
10. Describe the impact of marginal health literacy on medication adherence.
11. Identify the components of the medication therapy management (MTM) process.

INTRODUCTION

The roles and clinical impact of the pharmacist practitioner continue to evolve. One of the most exciting and rapidly growing areas of practice is **ambulatory care**, the environment in which the overwhelming majority of patients are seen at any given time. Ambulatory care, or the outpatient environment, encompasses not only **primary care** physician offices but also private clinics and hospital-based outpatient clinics, as well as community pharmacies to some extent.

In the contemporary model of pharmacy practice, ambulatory care pharmacists are involved in optimizing medication therapy outcomes while engaging with other healthcare professionals (see **Table 1-1**). Pharmacists working under a collaborative practice agreement with a physician have autonomy to engage in these practices within a defined scope of practice. A pharmacist can interview the patient to assess reasons for medication nonadherence, such as lack of understanding or affordability issues. In addition, the pharmacist can recommend immunizations that may be necessary to prevent further health problems. As the depth and breadth of clinical pharmacy education expands, so do the opportunities for pharmacists to be engaged in improving medication therapy, promoting safe use of medications, and assisting patients in gaining access to care.

DEFINING THE SCOPE OF AMBULATORY CARE PHARMACY PRACTICE

Ambulatory care involves providing healthcare services to patients who are able to walk, or ambulate, to the healthcare facility.¹ This provides the setting for provision of pharmaceutical care to promote health maintenance and prevention as well as to manage medication therapy for individuals with chronic diseases. Pharmacists have established a role in primary care ambulatory practice settings as well as targeted disease-focused clinics. Patients access primary care services at the initial point of access to receive treatment. Primary care treats patients with a broad range of ages and medical problems, and the practitioner assumes responsibility for referral and follow-up to other specialists (see **Table 1-2**). Ambulatory care practice settings deliver service at stand-alone clinics as well as clinics affiliated with healthcare systems.

Table 1-1 Contemporary Model of Pharmacy Practice

- Provide pharmaceutical care.
- Engage in patient-centered, outcomes-oriented pharmacy practice.
- Work with patients and other healthcare professionals.
- Promote health.
- Prevent and treat diseases.
- Assess, monitor, initiate, and modify medication use.

Source: Data from Schlaifer M, Rouse MJ. Scope of contemporary pharmacy practice: roles, responsibilities, and functions of pharmacists and pharmacy technicians. *J Manag Care Pharm.* 2010 Sep;16(7):507–8.

A definition of ambulatory care practice is provided in **Table 1-3**. In contemporary pharmacy practice, pharmacists are expanding their role from traditional areas, such as dispensing medication, counseling patients, and providing recommendations for self-care.² Contemporary practice involves the provision of direct patient care, with a renewed emphasis for pharmacists to be a member of the healthcare team.³ This paradigm is supported by the Institute of Medicine, which recognizes the value of an interdisciplinary environment to reduce medication-related errors. In contemporary practice, relationships between pharmacists and a single physician or groups of physicians can be formalized through collaborative practice agreements. The scope of practice is outlined for each provider; for example, once a patient's medical problem is diagnosed by the physician, the pharmacist adds or discontinues drug therapy and orders laboratory or other tests to monitor the patient.

Ambulatory care pharmacy practice is an integrated approach to patient care that embraces a partnership with the patient.² During each patient visit, pharmacists use a structured approach to interview the patient to elucidate subjective complaints and to gather objective data, such as vital signs, laboratory tests, and other test results. Pharmacists perform physical assessments to evaluate objective signs of disease. The pharmacist–patient partnership is strengthened through encouragement designed to motivate patients to take medications and to make healthy lifestyle changes. Pharmacists should be sensitive to poor literacy abilities and tailor their counseling by using clear language. Patients greatly appreciate a pharmacist's efforts to ensure that their medication regimen is affordable and/or covered by health insurance plans.

Table 1-2 Descriptions of Healthcare Professionals**Physicians: Medical Doctors (MDs) and Doctors of Osteopathy (DOs)**

- The first year after graduation from medical school the physicians are *interns*.
- *Residents* are doctors who are completing postgraduate training in their second and third years following graduation.
- Interns and residents comprise the *house staff* in a hospital.
- An *attending* is an experienced physician who oversees interns and residents.
- Both MDs and DOs use all accepted forms of medical treatment, including drug therapy and surgery.
- DOs emphasize holistic and preventive care.

Physician Assistants (PAs)

- Physicians may delegate medical duties to the PA that are within the physician's scope of practice and within the PA's training and experience.
- PAs may work on a physician–PA team in medical and surgical areas.

Nurses

- Nurses practice independently within their own defined scope of practice.
- Nursing roles range from providing direct patient care to managing cases, establishing nursing practice standards, developing quality assurance procedures, and directing complex nursing care systems.
- Expanding roles of nurses:
 - Nurse practitioners (NPs) conduct physical exams; diagnose and treat common acute illnesses and injuries; provide immunizations; and manage high blood pressure, diabetes, and other chronic problems.
 - Clinical nurse specialists (CNSs) provide specialized care such as cardiac, oncology, neonatal, and obstetric/gynecological nursing.
 - Certified nurse-midwives (CNMs) provide prenatal and gynecological care to normal, healthy women; deliver babies; and offer postpartum care.

Physical Therapists (PTs)

- Physical therapists provide therapies to improve the mobility of a person with physical disabilities, to relieve pain, and to prevent or limit the extent of a physical disability.
- Requires a masters degree or higher.

Respiratory Therapists (RTs)

- Care for patients with breathing or cardiopulmonary disorders.
- Minimum certification is the Certified Respiratory Therapist (CRT).
- Advanced certification is the Registered Respiratory Therapist (RRT).

Occupational Therapist (OTs)

- Provide therapies to improve the patient's ability to perform tasks in living and working environments.
- Use treatments to develop and recover the skills the patient needs for daily living and work.

Source: Data from Office of Occupational Statistics and Employment Projections. Occupational outlook handbook [Internet]. Washington, DC: U.S. Bureau of Labor Statistics; 2010. [cited Feb 10, 2012]. Available from: <http://www.bls.gov/oco/oco1002.htm#other>.

Ambulatory care arose because of the need to manage patients with chronic diseases that are treatable but not curable. Data collected in 2005 by the National Center for Chronic Disease Control and Health Promotion report that one in two individuals

report having a chronic illness.⁴ Pharmacists are likely to schedule visits with patients to provide **medication therapy management (MTM)** and preventive care strategies and to manage drug-related issues stemming from cardiovascular disease, chronic lower

Table 1-3 Definition of Ambulatory Care

Ambulatory care pharmacy practice is the provision of integrated, accessible healthcare services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management.

Source: Data from ACCP/APhA/ASHP Joint Working Group. A petition to the Board of Pharmaceutical Specialties recognizing Ambulatory Care Pharmacy Practice as a specialty. 2008 Nov.

Table 1-4 Definition of Pharmaceutical Care

. . . the responsible provision of drug therapy for the purpose of achieving specific outcomes that improve a patient's quality of life.

These outcomes are:

- Curing of a disease
- Elimination or reduction of a patient's symptoms
- Arresting or slowing of a disease process
- Preventing a disease or symptoms

Source: Data from Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990 Mar;47(3):533-43.

respiratory disease, and other areas. Ambulatory care involves managing patient issues regarding primary diseases, such as diabetes mellitus, as well as complications of diabetes, such as kidney failure.⁴

Pharmacists can use their clinical expertise to optimize medication therapy that ultimately meets the current demand for effective and efficient coordination of care. The definition of *pharmaceutical care* by Hepler and Strand emphasizes the pharmacist's responsibility to improve the patient's quality of life (see **Table 1-4**).⁵ The elements of care are aimed at improving the patient's immediate needs, such as improving the symptoms of disease. For example, patients with uncontrolled diabetes may experience symptoms of thirst caused by elevated blood glucose levels. By recognizing the significance of these symptoms while interviewing the patient, the pharmacist takes steps to design a plan to advance the doses of

prescribed medications or recommend new medication combinations. Using evidence-based medicine, a new drug regimen is chosen to lower blood glucose and achieve the desired target for hemoglobin A1C.

Pharmacists also consider drug therapy aimed at meeting long-term goals, such as reducing hospitalization and morbidity and mortality. Pharmacists must be aware that patients may place a higher value on medications that relieve symptoms of disease rather than producing long-term benefits, such as reducing hospitalizations or prolonging life.⁶ For example, a patient with heart failure may routinely take a diuretic dose to treat symptoms of edema. Most patients know that loop diuretics reduce signs of edema and improve symptoms associated with fluid retention. Often, they refer to these drugs as their "water pills." However, they may periodically skip doses or delay refilling prescriptions of other heart failure treatments because they perceive the medications to be unnecessary. Clinical trial evidence shows us that loop diuretics are effective in treating symptoms but do not offer the benefit of reducing morbidity and mortality as do angiotensin-converting enzyme inhibitors, beta-blockers, and aldosterone receptor antagonists. Pharmacists must be authoritative with patients and develop patient-centered messages to support adherence to all prescribed medications.

Pharmacists face challenges when translating scientific health information into a plan for the patient. The practice of pharmacy involves patient-centered MTM where the pharmacist is involved in setting goals to help the patient achieve beneficial therapy outcomes. For example, a patient diagnosed with type 2 diabetes has a goal of achieving a hemoglobin A1C (HgA1c) of less than 7%. In order to achieve this goal, the pharmacist educates the patient about the medical diagnosis to help the patient understand the relationship between the improved outcomes associated with achieving this goal. Pharmacists use their education and training to educate, coach, and motivate patients to adopt medication-taking behaviors and lifestyle changes while translating the evidence-based drug therapy plan into an acceptable message.

INDIVIDUAL CHARACTERISTICS NEEDED FOR AMBULATORY PRACTICE

Within the spectrum of professional competence and responsibility for pharmacists is the skill set that

governs the ability to provide patient care. The provision of sound patient care necessitates a solid foundation upon which the practitioner builds his or her practice. In other words, pharmacists need to not only master the informational foundations of drug and disease state knowledge, they also must be proficient in acquiring new information, using the primary literature to support therapeutic decision making, and personifying the qualities that make a pharmacist effective.

Information Mastery

Advances in medicine are constant, and these advances, when monumental enough, typically correspond to changes in therapeutic guidelines and standards of care. Because this is a dynamic process, it is paramount that pharmacists be proactive in staying current with the literature. Literature drives changes in practice, at least at a population level. This is referred to as **evidence-based medicine (EBM)**. Pharmacists also must be proficient in evaluating the literature and applying it appropriately to the *individual* patient. Providing adequate patient care involves the integration of evidence-based medicine and the practitioner's clinical judgment to treat the patient and achieve desired outcomes.

Personal Characteristics

Though the cognitive skills related to knowledge and evaluation of the literature are central to the success of the pharmacist as part of the healthcare team, emotional character and interpersonal skills also are vital. These skills include being compassionate, relating to the patient, showing empathy, and being responsive. Pharmacists actively listen to their patients so they can assess their perspectives on their illness and treatment as well as their level of understanding. **Figure 1-1** depicts the pharmacist engaging the patient in a discussion on the results from a finger stick blood glucose testing. A quiet setting is chosen to perform an MTM session to eliminate distractions. The pharmacist uses body language, a form of nonverbal communication, and maintains eye contact with the patient to demonstrate her focused attention. During an MTM visit, the pharmacist interviews the patient to determine medication **adherence** and any causes of nonadherence. Patients may have difficulty in dealing with their illness and may be unwilling to self-administer injectable drugs such as

insulin. A clinical pharmacist must develop an expertise in listening to patients to understand their perspectives on their disease or condition and to address any barriers to accepting therapy. Cognitive skills can be learned and emotional skills can be honed, but the real challenge is being able to coordinate all of these skills simultaneously and operationalize them during the patient encounter.

Healthcare professionals must embody personal characteristics that instill trust and confidence in their patients.⁷ Lessons to students who are in the early stages of professional development emphasize professional appearance and attitudes. Pharmacists should have a professional appearance, which can be achieved by wearing a clean, pressed white coat and business attire. These are the first steps toward becoming a professional where we ultimately hold ourselves accountable for the care of our patients.⁸

Pharmacists can speak persuasively to patients to motivate them toward adopting behaviors that promote wellness and health. Community pharmacists performing hypertension management were successful in improving outcomes by making persuasive recommendations to the patients' physicians to adjust therapy.⁹ During an advanced practice experience within the pharmacy curriculum, students can reflect on their interactions with patients and self-assess their ability to communicate effectively with enthusiasm and authority. Observations of skilled healthcare professionals can assist all of us in the self-reflection process,



Figure 1-1 Medication therapy management: Linking Pharmacists to Improved Health Outcomes (LPIHO).
Source: Courtesy of Williams Apothecary, Inc., Lancaster, Pennsylvania.

which will promote personal growth. An experienced pharmacist will firmly voice instructions with authority to patients regarding expectations on desired behaviors such as medication adherence and self-monitoring. The measure of an effective interchange between the pharmacist and patient is the patient's willingness to make positive changes.

Postdoctoral Credentials: Board Certification

After completing the traditional Doctor of Pharmacy program, more and more graduates are electing to pursue residency training and additional practice-setting or therapeutic area-specific credentialing. The Board of Pharmaceutical Specialties (BPS) administers board certification exams for specializations in pharmacotherapy, oncology, psychiatry, nuclear pharmacy, and nutrition support. Licensed pharmacists with experience in ambulatory care practice or postgraduate training are able to become board certified in ambulatory care.² This credential is a nationally recognized board certification that is typically part of the spectrum of expectations for pharmacists in clinical environments or in academia.

Being a Leader in the Field

Pharmacy often is described as a "small world," but despite the small size of our profession pharmacists can be found in almost every medical- and health-centered environment. It is our responsibility and professional duty to represent ourselves and our profession with the utmost compassion, motivation, and accountability, such that we can ensure that the practice of pharmacy becomes indispensable. Pharmacists should have a public presence as an advocate for patients and the profession.

Being a leader suggests the embodiment of the tenets of our profession. Leadership can involve overt achievements, such as gaining national recognition as an expert or serving in a national professional organization. It also may involve the development of new services or publishing outcomes- or practice-based research. Individuals who are involved with research may participate in the discovery of new drugs or dosage forms.

Other examples of leadership include modeling behavior for pharmacy students when they are

on rotation. These experiential components provide a tremendous opportunity for pharmacists to model behavior for pharmacy students and facilitate their transformation into practitioners. In this example, leading may take the form of demonstrating competent, compassionate patient care.

AMBULATORY CARE PRACTICE MODELS

Pharmacists are involved in a variety of ambulatory care practice settings. The literature includes reports of practices addressing chronic disease management, such as hypertension, diabetes, and asthma.^{10–12} Pharmacists working in these settings become specialists and often have additional certifications in these therapeutic areas. Pharmacists also serve as volunteers in free clinics to serve uninsured individuals.¹³ Indigent care clinics often are organized by a team of health professionals. Academic centers staff the centers with faculty members and offer this experience to students as a practice rotation. Practices can address the needs of specific groups, such as geriatric or pediatric patients. One clinic provides screening for metabolic syndrome to address the epidemic of adolescent obesity, which increases a person's risk of cardiovascular disease.¹⁴ Another novel adult outpatient clinic provides pain management for patients diagnosed with cancer.¹⁵ An example of a practice with a narrowly defined niche is an amiodarone clinic designed to prevent life-threatening side effects.¹⁶

Ambulatory care practice also is supported by government-sponsored health organizations. Pharmacist-managed clinics at the Veterans Affairs medical centers include practices focused on hypertension, anticoagulation, primary care and general medicine, and lipid management.¹⁷ Patients with mental health needs are cared for at a mental health clinic and a clozapine management clinic.¹⁸ The mission of pharmacists in the U.S. Public Health Service (PHS) Commissioned Corps is to serve underserved groups with medical needs.¹⁹ PHS pharmacists provide pharmaceutical care in chronic care clinics through the Indian Health Service to serve the needs of Native Americans. PHS pharmacists also work with the Federal Bureau of Prisons, where there is a significant need for managing inmates with human immunodeficiency virus (HIV).

Ambulatory care pharmacists are involved in preventive care, primary care, and chronic disease management, delivering pharmaceutical care to pediatric and adult populations. Ambulatory care pharmacists respond to the healthcare needs of Americans by implementing novel clinics to address emerging health issues.

Community Setting

Ambulatory care practice is evident in the community pharmacy practice setting. A landmark study evaluated pharmaceutical care tailored to a specific population and disease state. The Asheville Project conducted in Asheville, North Carolina, demonstrated that community pharmacists were effective in providing pharmaceutical care to individuals from a self-insured employer. A novel disease management program was implemented at 12 community pharmacies and hospital clinics using pharmacists to deliver MTM to patients with hypertension and dyslipidemia.²⁰ The program was supported by two large employers, the City of Asheville and Mission Hospitals, which gave incentives to patients by reducing or waiving medication co-payments. Patients met with pharmacists for 30-minute visits every 3 months for up to 6 years and attended educational classes on cardiovascular risk reduction. These interventions significantly improved blood pressure ($p < 0.0001$) and resulted in a 53% decrease in cardiovascular, cerebrovascular, and peripheral vascular events (odds ratio 0.47 [95% CI 0.328–0.671]).²⁰ The Asheville Project was a pivotal study in providing support for the role of community pharmacists in providing comprehensive disease management and demonstrating the economic value of community interventions.

The Appointment-Based Model

New approaches are redesigning the interface where pharmacists interact with patients for dispensing medications. An innovative model being piloted in community pharmacy practices promotes the pharmacist–patient relationship and facilitates the integration of MTM in that setting. The appointment-based model, formerly known as the patient-centric model, involves scheduling monthly or quarterly appointments with patients to refill

all medications. Implementation of the model is being beta-tested by the National Alliance of State Pharmacy Associations. Synchronized prescription fills will have a positive impact on patients with chronic diseases who currently require frequent medication refills. The aim of the appointment-based model is to improve patient persistence in taking medications.²¹ This model changes the paradigm for community pharmacy and allows for more opportunities for patient counseling and MTM.

Transitions of Care

Ambulatory care pharmacy practice also can encompass transitions in care settings. The growing geriatric population is rapidly changing the healthcare environment. Because of the measurable impact the geriatric population has on healthcare resources, healthcare policymakers are now focusing on the medical home model of care.²² Primary care practitioners are needed to coordinate care because patients are seen by multiple healthcare specialists and also transition from the hospital to home. In the medical home model, pharmacists work with physicians, nurses, physician assistants, physical therapists, occupational therapists, and others. **Medication reconciliation** involves identification of potential medication-related problems, such as duplicate therapy, or untreated indications and is a step toward reducing unnecessary rehospitalizations.

Senior Care Pharmacist

Senior care pharmacists are experts at anticipating and preventing geriatric syndromes associated with drug misuse in the elderly. They have a specialized knowledge in geriatric pharmacotherapy and understand that elderly patients often respond differently to medications than relatively younger adults. Patients visiting primary care physicians as well as specialists are at risk for duplicate therapy and **polypharmacy**, a situation where patients are prescribed an excessive number of medications. For example, a patient with a new complaint of urinary frequency may be inappropriately treated with a urinary antispasmodic because healthcare providers ignored medical records documenting a recent dose increase in a diuretic.

Senior care pharmacists may work as consultants in long-term care settings, but their skills are transferable to many other settings, including the medical home model and hospice. Consultant pharmacists evaluating older adult patients in the community identified the need for at least one medication change in two of every three patients.²³

AMBULATORY CARE PRACTICE PROCESSES

Ambulatory care pharmacy services should incorporate specific MTM processes to achieve therapeutic outcomes (see **Table 1-5**).²⁴ It is important to distinguish the differences between traditional roles that are tied to medication dispensing versus models involving MTM. The term *patient counseling* describes a one-time educational intervention offered to patients at the time of medication dispensing. In contrast, MTM describes a comprehensive process involving repeated

follow-up with patients. MTM requires in-depth documentation of patient encounters and interactions with other healthcare professionals.²⁵

Patient Counseling

The Omnibus Budget Reconciliation Act of 1990 (**OBRA '90**) established the legal foundation for prospective drug utilization review (DUR) as well as mandatory pharmacist counseling to Medicaid patients.²⁶ Subsequently, some states passed similar regulations that broadened the use of DURs to a wider population. Pharmacists must concurrently review medications that are dispensed to determine the appropriate or inappropriate use of the medications based on the indication, dose, and duration of therapy (see **Table 1-6**). Pharmacists also determine the safe use of a drug based on the presence of contraindications or allergies, drug–drug or drug–nutrient interactions, or potentially serious adverse reactions.

Table 1-5 The Core Elements of Medication Therapy Management

Core Element	Description	Outcomes
Medication review	Patient brings in all medications (prescription and OTC) and pharmacist evaluates regimens for appropriateness.	Appropriate medication, dose, and dosing regimen are identified. Unnecessary medications are identified. Adherence to medication therapy is evaluated. Untreated conditions are identified. Medication costs are evaluated. Education on appropriate use of medications and importance of medication adherence is provided.
Personal medication record (PMR)	Patient receives a record of all current medications.	Patient is encouraged to be active in his or her own medication management.
Intervention or referral	When drug-related issues are identified, the pharmacist will intervene and collaborate with the physician to resolve existing medication-related problems.	Tools/aids are recommended for patients who require help in organizing their medicines. A physician referral is made when the problem is complex or multifactorial.
Documentation and follow-up	Pharmacist will document and provide feedback to the physician of the findings and outcome.	Continuity of care is enhanced and the pharmacist is established as a member of the healthcare team.

Source: Data from McGivney MS, Meyer SM, Duncan-Hewitt W, Hall DL, Goode JV, Smith RB. Medication therapy management: its relationship to patient counseling, disease management, and pharmaceutical care. *J Am Pharm Assoc.* (2003). 2007 Sep–Oct;47(5):620–8.

Table 1-6 OBRA '90 Prospective Drug Review

Appropriate use:
• Indication
• Dose
• Duration of therapy
Therapeutic duplication
Safety:
• Allergy
• Contraindications
• Adverse reactions
• Interactions

Source: Data from Fulda TR, Lyles A, Pugh MC, Christensen DB. Current status of prospective drug utilization review. *J Manag Care Pharm.* 2004 Sep-Oct;10(5):433-41.

Pharmacists must give instructions for administering medications and counsel patients when new prescriptions are dispensed. In addition, if medication-related problems are present then the pharmacist must take action by counseling the patient or contacting the prescriber to perform a clinical intervention. Pharmacist counseling increased from 37% in 1982 to 42% in 1994; as of 2000, more than two-thirds of pharmacists performed counseling.²⁷ OBRA '90 was helpful in formalizing the role of pharmacists and increasing awareness to the general public and other healthcare professionals.

Medication Therapy Management

With the advent of the Centers for Medicare & Medicaid Services' (CMS) development of the concept of medication therapy management (MTM), thousands of patients became eligible for a novel and potentially cost-saving pharmacist-provided service. MTM, by definition, involves the systematic collection of patient information, medication therapy assessment, development of a medication-focused problem list, and the creation of a therapeutic plan. Although already performed by pharmacists in many practice settings, MTM involves formalized documentation of all patient encounters and therapeutic plans as well as collaboration and ongoing communication with physicians (see Table 1-5 and **Table 1-7**). The delivery of MTM presents an important opportunity for pharmacists in both inpatient and outpatient practice settings to truly collaborate with physicians as well as to practice many of the clinical, assessment, and patient- and practice-management skills that are intrinsic in pharmacy practice. The intended outcome of

MTM services is to optimize patient care by either preventing or identifying and resolving medication-related problems. It is a medication-focused assessment performed by a pharmacist but executed in collaboration with a physician; it is an interdisciplinary approach to patient-centered care.

Collaborative Drug Therapy Management

A drug therapy management protocol describes the scope of practice for the pharmacist in a clinic.^{28,29} The authority for pharmacists to prescribe medications is based on state regulations.³⁰ The drug therapy management protocol must abide by the law and describe the areas in which authorization is agreed upon by the collaborating physicians. When approved by state regulations, the scope of practice should define if the pharmacist is able to initiate drug therapy or whether this function will be within the scope of the physician. Pharmacists will be involved in assessing drug therapy, initiating or modifying therapy, and ordering laboratory and other tests.

A **collaborative practice** agreement is a formal, written protocol developed by the physician and pharmacist. In practices involving more than one healthcare professional, these practice agreements may apply to more than one physician or pharmacist. The practice agreement describes the scope of practice and responsibility of the pharmacist for performing MTM.³¹ Pharmacists also should be aware of the role of other healthcare professionals because they are involved in evaluating and referring patients to others (see Table 1-2).

Problem Assessment

The identification of problems through an accurate and comprehensive assessment is essential for developing the therapeutic plan. Problem assessment includes recognizing drug- or medication-related problems and communicating with the patient's physician or collaborating physician to recommend modifications. The ideal assessment method should succinctly articulate the problem and the corresponding action plan.

The literature assists healthcare providers in performing assessments of medical problems across multiple dimensions that include staging, classification, or severity. For example, a patient with two blood pressure readings over 140/100 mm Hg who is not taking

Table 1-7 Potential Drug Therapy Problems

- Medication used with no medical indication.
- Patient has medical conditions for which either no medication or a nonmedication therapy has been prescribed.
- The prescribed medication or nonmedication therapy has been prescribed inappropriately for a particular medical condition.
- The immunization regimen is incomplete.
- The current medication therapy regimen includes something inappropriate (dose, dosage form, duration, schedule, route of administration, method of administration).
- There is therapeutic duplication.
- A medication to which the patient is allergic has been prescribed.
- There are adverse drug- or device-related events or the potential for such events.
- There are clinically significant drug–drug, drug–disease, drug–nutrient, or drug–laboratory test interactions or the potential for such interactions.
- Medication or nonmedication therapy has been affected by social, recreational, or nontraditional drug use by the patient or others.
- The patient is not receiving the full benefit from the prescribed medication or nonmedication therapy.
- Problems have arisen due to the financial impact of the medication or nonmedication therapy on the patient.
- Patient lacks understanding of the medication or nonmedication therapy.
- The patient is not adhering to the medication or nonmedication therapy regimen.

Source: Data from van Mil JW, Westerlund LO, Hersberger KE, Schaefer MA. Drug-related problem classification systems. *Ann Pharmacother*. 2004 May;38(5):859–67.

any medications would be assessed as having stage I hypertension. Chronic conditions such as heart failure, kidney disease, and liver disease also can be classified or staged. As another example, the CURB-65 tool was developed to differentiate severe pneumonia requiring hospitalization versus less severe forms that can be treated on an outpatient basis.³²

A single cohesive system for assessing drug-related problems does not exist, but a variety of methods are available. One streamlined problem-assessment method uses three broad categories: indication, appropriateness, and safety.³³ This is a quick system for organizing thoughts about medication-related problems.

The method suggested by Cipolle, Morley, and Strand offers seven categories for drug-therapy problems (see Table 1-8). The system adopted by the American Society of Health-System Pharmacists is a modification of the original system created by Hepler and Strand (see Table 1-8). Hepler and Strand describe eight different categories, including “drug interactions,” reflecting the root cause of the problem, and “failure to receive drugs,” reflecting potential problems stemming from medication nonadherence or failure to fill prescriptions.³⁴ Cipolle, Morley, and Strand created subcategories under the eight categories to point toward the cause of a problem or to define the specific problem. For example, if the wrong drug was chosen,

Table 1-8 Classification of Drug-Therapy Problems

Cipolle, Strand, and Morley Classification

- Need for additional therapy
- Unnecessary therapy
- Wrong drug
- Dose too low
- Adverse drug reaction
- Dose too high
- Adherence problem

Hepler and Strand Classification

- Untreated indications
- Improper drug selection
- Subtherapeutic dosage
- Failure to receive drugs
- Overdosage
- Adverse reactions
- Drug interactions
- Drug use without indications

Sources: Data from Cipolle, RJ, Strand, LM, Morley, PC. *Pharmaceutical care practice: the clinician’s guide*. 2nd ed. New York: McGraw-Hill; 2004; and van Mil JW, Westerlund LO, Hersberger KE, Schaefer MA. Drug-related problem classification systems. *Ann Pharmacother*. 2004 May;38(5):859–67.

the pharmacist could document the cause as a preexisting drug allergy or inappropriate dosage. Note that one disadvantage with the method offered by Cipolle, Morley, and Strand is that financial or affordability issues are not included as a separate category, and these are relevant concerns. The categories offered by Cipolle, Morley, and Strand allow for specific documentation of the problem and can facilitate the tracking of pharmacist interventions.³⁵ The classification method is data intensive, but it can be implemented with a guide or computer-based data entry system.

The process of problem identification involves a critical analysis of symptoms due to medical problems and conditions as well as from drug-induced causes. The practitioner should spend additional time scrutinizing the problem list and assessment to look for interconnections between problems. For example, a heart-failure patient presenting with an acute gout attack may actually be experiencing a drug therapy problem if he or she is taking high-dose loop diuretics. For students and new practitioners who are just beginning to master their personal database on drug therapy, taking a “second look” at the problem list can prompt them to consider the impact of organ dysfunction, such as kidney or liver impairment, that necessitates dose modifications. For example, in a patient with diabetes and chronic kidney disease, careful consideration of all of the patient data will ensure that the practitioner does not overlook recommendations to discontinue metformin in patients with serum creatinine levels above the threshold values.

Developing a Plan

Development of an appropriate plan for medication therapy involves medication selection and managed care considerations.

Medication Selection

The strategy involved in the selection of medication therapy is highly variable and depends on the disease state and the patient in question. However, a few tenets should be considered whenever a drug therapy plan must be developed and implemented. The first consideration is the use of evidence-based clinical guidelines or reputable primary literature to support decision making. It is assumed that the clinician will apply therapeutic guidelines whenever they exist. For example, if a patient is diagnosed with hypertension, then the accepted guideline is the JNC-VII (The

Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure). Its recommendations were derived from clinical trials and compiled by experts into a clinician-friendly set of guidelines, treatment considerations, and algorithms.

The second consideration in selecting medications is efficacy. If a guideline exists for a disease state, then theoretically the medications that appear in the hierarchy have been proven safe and efficacious. However, clinical experience and new evidence may influence the clinician’s interpretation of the stated efficacy. Some medical conditions do not have clear-cut guidelines, and in this case a clinician uses his or her clinical experience and knowledge of accepted uses to select a medication. For example, a patient diagnosed with an anxiety disorder could theoretically be treated with any one of about six or seven drug classes. Existing guidelines endorse two of those classes as first-line therapies. The clinician must make an informed decision regarding the optimal first-step therapy based on the guideline and his or her understanding of the effectiveness of a particular medication to achieve clinical benefits and meaningful patient-oriented outcomes, such as reduced morbidity and mortality. Choices also may be affected by a health-system drug formulary or the formulary of the patient’s health insurance program.

Safety is the third consideration. Drug classes and individual drugs are associated with adverse effects and safety issues that may impact a patient’s concomitant disease states or medications, quality of life, clinical outcome, or adherence. Careful evaluation of commonly experienced adverse effects as well as rare but serious adverse effects must be considered prior to initiating therapy. A patient suffering from severe psoriasis may be a candidate for a biologic therapy based solely on the severity of the disease, but the patient may have a history of malignancy and therefore the risks likely outweigh the benefits. In another example, a patient starting on a novel oral anticoagulant should be carefully monitored for changes in objective parameters, such as laboratory results. It is the pharmacist’s responsibility to identify situations when dosing must be modified due to organ dysfunction affecting drug metabolism or elimination. Pharmacists must keep up with the literature so they are aware of newly approved drugs and emerging case reports describing adverse reactions and drug interactions. A clinical and administrative responsibility involves reporting adverse drug reactions using the

health-systems' program or reporting to MedWatch, the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting program.

Lastly, cost may impact drug selection. Ideally the ability to afford a medication should not influence the efficacy, safety, and evidence-based medicine-driven selection process. In reality though, if a patient cannot afford a medication and is unable to obtain the drug, then no benefit can be derived. Sometimes a compromise must occur in that the prescriber may select a slightly less efficacious drug or a less ideal drug in order to ensure that the patient will be able to obtain it.

Managed Care Considerations

One of the most common issues underlying patients' inability to purchase medication are restrictive formulary practices that influence pricing, reimbursement, cost sharing, and co-pays, all of which can delay the patient's acquisition of the medication. Formulary restrictions represent a constellation of cost-containment modalities that are designed to control drug-related spending for managed care organizations. Among the most conventional of these restrictions are prior authorization requirements, tiered formularies, and step-therapy requirements. Prior authorizations require that physicians provide documentation supporting their rationale for selecting a nonformulary drug, and only after review will the prescription be covered. Tiered formularies are developed such that the more expensive, non-preferred drugs are in a higher tier or level (usually designated in such a way that tier 5 would be more costly than tier 2), resulting in either a higher co-pay or denial of the claim. Generic products tend to be in the lower tiers, whereas costly brand names are generally in the higher tiers. Step therapy refers to an automated review process generated by the pharmacy benefits manager (PBM) at the point of service. The automated step-edit review, or "smart edit," searches the patient's claims history for evidence of a prior claim for a drug from the step-edit preferred class. Absence of a prior claim for a drug in a preferred class prompts a rejection of the current claim. The intention of these administrative actions is to encourage the use of generic drugs or less expensive alternatives over branded drugs or costly therapies without compromising the quality of care. Progression to more expensive alternatives is contingent upon either clinical failure of the initial drug or drug class or a prior authorization submission

by the prescriber. Failure to adhere to the formulary restriction paradigm generally results in higher out-of-pocket expenses for the patient as a form of retribution for abandoning the formulary hierarchy.

PATIENT-CENTERED INTERVIEWING

The patient interview is a critical component of the healthcare process. It provides for a methodical, meaningful exchange of relevant health and socio-demographic information between the patient and provider. The interview is the mechanism through which a diagnosis is established, rapport is developed, the patient-provider relationship is cemented, and the therapeutic plan is communicated. The strength and quality of this interaction will directly influence the ongoing relationship between the patient and healthcare provider, and it may impact clinical outcomes as well. Motivational interviewing is a method to promote awareness of barriers that impede acceptance of treatment interventions and engage the healthcare professional in assisting the patient in understanding the benefits of accepting the recommendations and adapting new behaviors to improve health outcomes. Patients who feel comfortable with their providers and have developed an appropriate level of trust are more likely to be adherent to therapy and more involved in their care.

A new qualifier—*patient-centered*—has been added in response to the biopsychosocial approach to health care. It represents a more humanistic approach to the patient that incorporates not only the biology of the problem but also the psychological and social dimensions of the patient. The historical approach to interviewing the patient is now referred to as *clinician-centered*, reflecting that the healthcare provider typically leads the session, asks pointed questions, and obtains data relevant to the presenting problem. In contrast, with the patient-centered interview, the clinician maintains control over the encounter in terms of flow, but the patient is responsible for most of the communication.

Approach to the Patient

With the patient-centered interview, the clinician uses an open-ended questioning style that promotes a more complete dialogue from the patient. Open-ended questions do not elicit one-word answers but rather encourage more comprehensive answers that lend themselves well to discussion. An example of this

would be a clinician asking the patient to “describe” a symptom or “explain” a scenario. The clinician may employ several techniques to facilitate the patient-centered approach. Maintaining attention but remaining silent; offering nonverbal encouragement, such as nods or smiles, and neutral vocal acknowledgments (e.g., “yes”, “uh huh”); and summarizing the patient’s account for purposes of confirmation are examples of techniques used in patient-centered interviews.

Developing a Covenantal Patient–Provider Relationship

Developing trust and a rapport with the patient is a foundational component of the patient care process. Central to this theme is the mutual trust that must be endorsed by both parties. An unspoken expectation exists that patients will be forthcoming with their personal health information. We expect patients to share their honest attitudes and beliefs regarding the acceptance of care. Healthcare providers must treat all information confidentially and take steps to ensure that the information is kept private. Another expectation is that the healthcare provider has moral, ethical, and professional obligations to apply his or her knowledge and expertise to the care process. There also is an expectation of competence on the part of the healthcare provider.

Fostering Partnerships

In addition to increased patient participation, the patient-centered approach incorporates the attitudes and beliefs of the patient into the evaluation and plan. Optimal care is best generated by a true “team,” one that includes the healthcare professionals (e.g., physicians, pharmacists) as well as the patient. Inclusion of the patient on the team enhances clinical outcomes and improves the patient experience. During a patient encounter, particularly when drug therapy is recommended, it is good practice for the clinician to ask the patient about his or her thoughts about and acceptance of initiating a medication. Keep in mind that the healthcare provider is in the unique position of having the knowledge, experience, and clinical expertise to make treatment-related decisions and must maintain that control. However, engaging the patient and ascertaining his or her commitment to taking the medication will positively impact the success of the plan. Remember that recommending drug therapy is only the

first step. If patients do not believe in medications or are not completely educated about the rationale and benefit of taking a particular medication, then they may not adhere to the plan or they may not use the medication at all. Assessing the patient’s beliefs about medications and making sure that he or she “buys in” to the plan and is actively a part of developing the plan is essential.

Oftentimes patients are not adequately forthcoming about the severity of their symptoms or the extent to which they impact their life. Simple questions such as “How does your asthma impact your ability to play with your children?” or “How has your diabetes diagnosis affected your social life?” or “How do your symptoms make you feel?” may elicit a much more multidimensional assessment than simply asking a patient to comment on whether he or she is experiencing symptoms.

Once patients are comfortable enough to incorporate their feelings into their dialogue, it is the responsibility of the clinician to appropriately accept, interpret, and respond to those feelings. For example, a patient suffering from depression may express extreme emotion when prompted, and the clinician needs to respond to the emotion in such a way that the patient is reassured. Offering tissues, providing reassurance, practicing active and empathic listening, praising the patient’s ability to share emotions, and even self-disclosing (discussing personal or professional circumstances that are similar to the patient’s situation, within reason) will make the patient feel that he or she is being heard and that the message has been well received. This often is a challenge for pharmacy students and new practitioners because the incorporation of emotions has not always been considered a traditional part of the healthcare process. Emotion also can surface during unlikely circumstances. We think of emotions as being an accepted and expected part of the spectrum of mental health or terminal illness but not necessarily part of chronic, nonfatal disease assessment. Despite this, clinicians should actively elicit emotion from the patient whenever possible.

Health Literacy

A significant percentage of adults in the United States have limited literacy abilities. The percentage of adults with “below basic abilities” in reading written words and documents is 14%.³⁶ Quantitative skills are somewhat worse and have improved in the last 20 years. The percentage of adults in the United

States with below basic abilities for number interpretation is 22%. These individuals are functioning at a third-grade level. These skills carry over to an individual's ability, or inability, to read, interpret, and act on health information, which is referred to as a person's **health literacy** level. Poor health literacy increases the likelihood that a person will require healthcare services from a public-funded healthcare program.³⁷ In addition, the healthcare costs of those with low health literacy levels are much greater than those with adequate health literacy. A low health literacy level presents a barrier to understanding written and verbal instructions. At the most basic level, patients may not be able to interpret the information typed on their prescription vial. Patients often struggle to name their medications because many brand and generic drug names are multisyllabic words that are difficult to pronounce.

Health literacy also extends to the ability to understand numerical risks presented as ratios or percentages used to describe risks of disease or risk of treatment outcome. A person must be able to accurately interpret these values in order to make informed decisions about treatment choices. Tools are available to assess a patient's health literacy level. A practical tool that can be used for a quick assessment is the Newest Vital Sign, which asks the patient to interpret a Nutrition Facts label.^{38,39}

Pharmacists can be sensitive to the communication barrier presented by poor health literacy by delivering health messages using clear language. This means simplifying language, avoiding jargon, and defining health-related acronyms (e.g., CABG for coronary artery bypass graft). Visual tools such as pictures, diagrams, and charts can be incorporated into patient education sessions to help patients interpret medication instructions. Ambulatory care pharmacists at a heart failure clinic were able to improve medication adherence and reduce emergency department visits in patients with low health literacy by scheduling frequent patient visits and providing individualized information.⁴⁰

Medication Adherence

Medication adherence equates to the patient taking the medications that are prescribed by their healthcare provider.⁴¹ A patient who is adherent is active in accepting the treatment plan; the patient willingly follows instructions from healthcare providers and accepts responsibility for maintaining his or her

health. The preferred term is *adherence*; the former term, *compliance*, is discouraged because it has negative connotations about the individual being a "noncomplier." In order to study adherence rates, the percentage of medications taken over a given time period are reported. Adherence rates should be greater than 80%.^{41,42} Adherence also relates to taking medications on time during any given day.⁴²

Healthcare providers may rely on patients' self-reporting of adherence, which is the least accurate method for determining adherence. Patients often are forgetful and may only recall recent lapses in medication taking. Psychological factors also play a role in self-reporting because patients want to appear agreeable as they anticipate the social desirability of the response.⁴³ Measurement of drug levels is a more reliable method of determining adherence. Many studies evaluating adherence rates use prescription refill rates, which may or may not be available at the point of care.

Pharmacists have to play "detective" if they suspect drug nonadherence because the reasons for nonadherence may not be immediately apparent. One validated tool developed for use in patients with hypertension is the Morisky scale, which uses a number of questions to root out the causes of nonadherence.⁴⁴ Barriers to adherence often include forgetfulness, troublesome side effects, or affordability. Cognitive factors, such as dementia or depression, can impact medication-taking behaviors. Pharmacists can assist patients with limited financial resources in identifying the most appropriate insurance or indigent care program, determining Medicare or Medicaid eligibility, or providing information on the "Extra Help" Medicare program.⁴⁵

Challenging situations occur when individuals are in denial about their medical diagnosis or do not value current pharmaceutical treatments. For example, hypertension is an asymptomatic disease; symptoms arise only when the disease progresses to the stage of target organ damage. Individuals may hold health beliefs that are negatively influenced by observations of others seeking treatment. For example, asthma is a highly prevalent disorder that can be lethal due to acute asthma attacks. A patient who has observed a friend or family member suffering from an asthma exacerbation may erroneously link standard treatment with the poor outcome. For these reasons, the patient may be unwilling to adopt the recommendations offered.

Pharmacists can target a number of areas to improve adherence. They can offer clear medication-taking instructions regarding drug administration, scheduling, and duration of therapy. Instructions should emphasize the goals of therapy and the direct benefits of treatment regarding symptom improvement. For example, antibiotics used for bronchitis are more effective and recurrences are less likely if the patients take the full course of therapy. Pharmacists can strengthen the patient–pharmacist partnership by inquiring about the patient’s personal preferences and beliefs about treatment. In one study, patients with heart failure were split; some valued taking action to improve quality of life whereas others felt the imperative to adhere to medications to prolong life expectancy.⁶

Patients may need assistance in organizing their medications at home. On average, individuals with heart failure take 9 to 12 medications a day.⁴² Pharmacists can select and recommend dosage forms to simplify the medication regimen.⁴⁰ Many drugs are available as a sustained-released product that can be taken once a day. In reviewing a patient’s medication list, over-the-counter or complementary and alternative medications may be inflating the total pill burden and complicating the regimen. By involving the patient in the decision-making process, the pharmacist can engage the patient in a discussion of stopping unnecessary drugs.

When discussing the patient’s home medication system, the pharmacist can make suggestions for placing medications in a spot that will help the patient with his or her medication-taking routine. Placing a prescription vial in the kitchen can help the patient link taking the medication with a meal, such as breakfast or dinner. Placement in the bedroom would remind the patient to take the medication at bedtime.

Individuals with chronic diseases are at risk for polypharmacy and may benefit from having a “retired medication” drawer in their home. Healthcare

providers are aware that medications are costly and that patients may be unwilling to discard medications. However, by placing unneeded medications in an “inactive” spot, they can avoid inadvertent drug administration of a discontinued medication.

For tech-savvy patients, alarms on watches, phones, or personal digital devices can be a reminder to take a dose. Family members or friends can be recruited to assist the patient, especially if the individual is subject to forgetfulness or has dementia. Pillboxes can be used to sort medications into three or more daily, divided portions or into one daily portion. However, patients should be carefully selected for using a pillbox. Once the box is upturned and dosage forms spill on the floor, it can pose a challenging situation.

NAVIGATING THIS TEXT

Clinical Therapeutics Primer: Link to the Evidence for the Ambulatory Care Pharmacist is intended to assist the reader in navigating through some of the approaches to handling commonly encountered outpatient medical conditions. Organized by disease state, each chapter provides background on the condition, a review of pivotal literature, and guidelines for standards of care. The chapters reinforce therapeutic concepts and models critical thinking through the use of patient cases. Throughout the text, “Clinical Pearls” gleaned from professional practice offer additional insights for the new practitioner. The book should be used as a guide, a “how to” manual of sorts, that will ideally lay the foundation for the reader’s approach to patient care in the ambulatory setting. We challenge the reader to master the cognitive and the emotional skills that make the pharmacist not only competent but also exceptional. Further, it is our hope that this integrative model of patient care will help students and new practicing pharmacists advance the practice of ambulatory care pharmacy.

DISCUSSION QUESTIONS

1. What are the advantages and disadvantages of using tablet-splitting as a managed care policy?
2. Describe an approach to educate a patient with poor reading ability who is receiving treatment for a lipid disorder. Develop a plan for explaining the patient’s diagnosis and his or her lipid goals.
3. A 68-year-old patient who lives with one of her adult children is having difficulty remembering to take her prescription medications. She frequently forgets to take her medications in the morning and evening. Formulate a plan for counseling this patient on medication adherence.

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