Koda-Kimble & Young's

Applied Therapeutics

The Clinical Use of Drugs

TENTH EDITION

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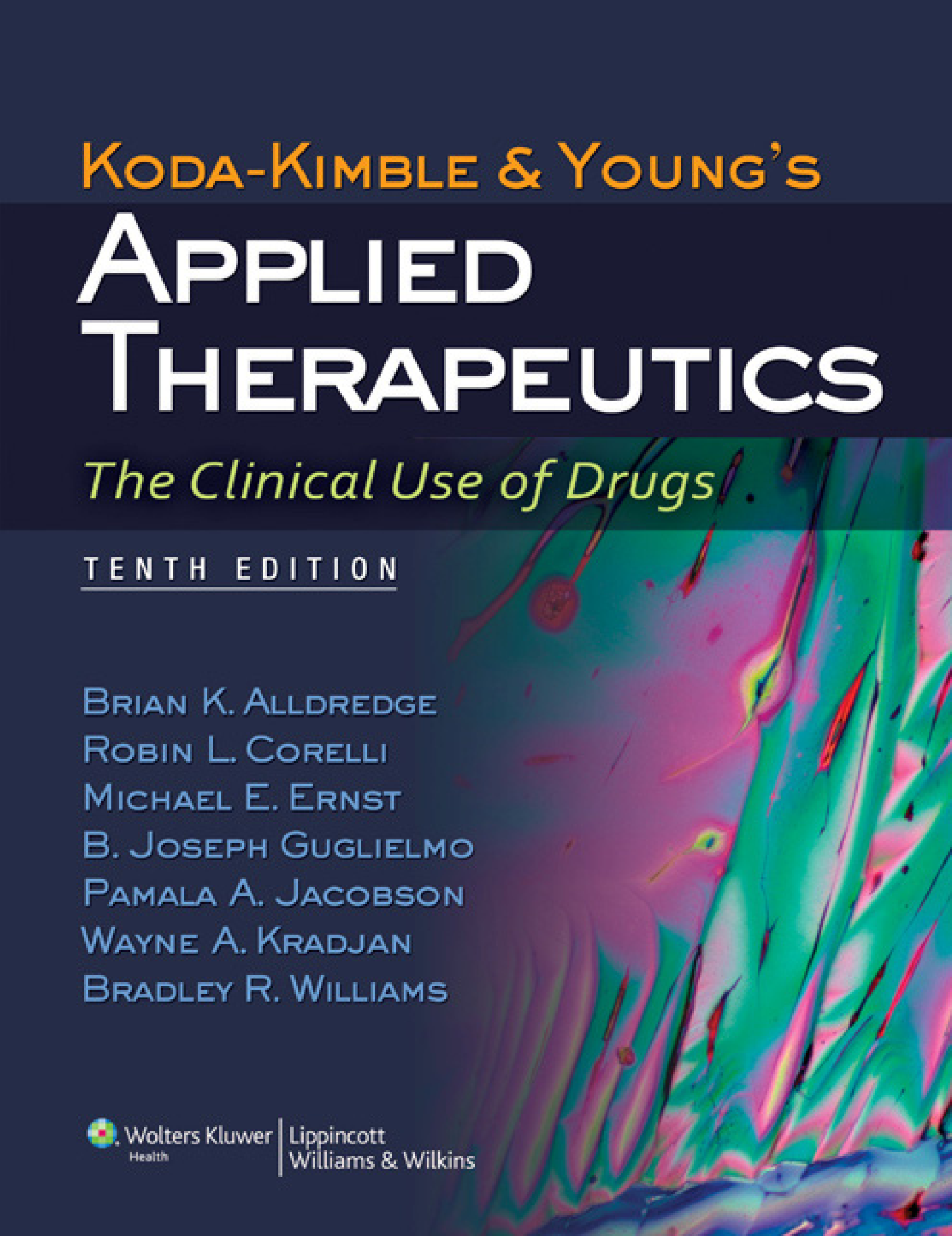

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TENTH EDITION

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Dedication

The Editors wish to express their sincere thanks and longstanding admiration to the creators of Applied Therapeutics, Drs. Mary Anne Koda-Kimble and Lloyd Young. They are truly educational visionaries whom we deeply respect as the innovators and pioneers in the teaching of patient-centered drug therapeutics. Their passion has touched the lives of countless health care professional students, clinicians, and patients throughout the world. As their colleagues and friends, we are forever indebted for their contributions and we consider it a privilege to carry forward their legacy—renamed as Koda-Kimble and Young's Applied Therapeutics*—into future editions.*

Preface

It has been nearly 40 years since the first edition of *Applied Therapeutics: The Clinical Use of Drugs* was published. The landscape of health care has evolved radically during this time, much of it spurred by remarkable advancements in drug discovery and clinical therapeutics. Despite these changes, the founding principle for this innovative text—a patient-centric, case-based approach to learning—remains integral to the current edition. Our authors present more than 860 patient cases that stimulate the reader to integrate and apply therapeutic principles in the context of specific clinical situations. Students and practitioners are provided with a glimpse into the minds of clinicians as they assess and solve therapeutic problems toward the development of their own critical-thinking and problem-solving skills. Every chapter in this edition has been revised and updated to reflect our ever-changing knowledge of drugs and the application of this knowledge to the individualized therapy of patients. Additionally, content within several sections has been extensively reorganized, with new chapters introduced to expand important topics. Among these are new chapters in the Arthritic Disorders, Women's Health, Neurologic Disorders, Neoplastic Disorders, and Pediatrics sections.

Readers familiar with past editions of the text will notice some welcome changes in the tenth edition. The overall design has been updated for visual appeal and to allow the reader to more quickly distinguish cases from surrounding text. In lieu of the traditional chapter outline, all chapters now contain a Core Principles section at the beginning, which provides the most important "take home" information from the chapter. Each Core Principle is mapped to specific cases within the chapter where the principle is discussed in detail. Key references and websites are listed at the end of each chapter, whereas the full reference lists for each chapter have been moved online.

A particularly significant change to the tenth edition is the incorporation of online multimedia content, much of it author-created, for many of the chapters. These include images, videos, narrated presentations, animations, and podcasts, which can be found on the textbook's website (see the "Additional Resources" section, which follows this preface, for more information). The incorporation of supplemental multimedia into the tenth edition marks a commitment on the part of the editorial team to ensure that *Koda-Kimble and Young's Applied Therapeutics* increases its role as a viable and dynamic resource that can appeal to multiple learning styles and future generations. We welcome your feedback as we undertake planning for the next edition.

The authors have drawn on information from the literature, current standards, and their own clinical experiences to share the process involved in making sound and thoughtful therapeutic decisions. *However, it remains the responsibility of every practitioner to evaluate the appropriateness of a particular opinion in the context of the actual clinical situation, bearing in mind any recent developments in the field. We strongly urge students and practitioners to consult several appropriate information sources when working with new and unfamiliar drugs.*

ACKNOWLEDGMENTS

We are deeply indebted to the many dedicated people who have given of themselves to complete the tenth edition of *Koda-Kimble and Young's Applied Therapeutics*. As always, we are most grateful to our contributing authors who have been attentive to meeting our stringent time deadlines and unique writing format. We especially thank those authors who graciously provided multimedia to accompany their chapter, and we gratefully recognize the additional time and effort this entailed. We hold their creativity in the highest regard. The exceptional work of our section editors, Judith Beizer, Marcia Buck, Shareen El-Ibiary, Marcus Ferrone, Patrick Finley, Timothy Ives, Mark Kirstein, Lisa Kroon, Kelly Lee, Myrna Munar, Jean Nappi, Tricia Russell, and Joseph Saseen, cannot be overstated. These content experts gave us critical feedback necessary in both the organizational structure of the textbook and in the individual editing of chapters; without their dedication and assistance, this edition would not be possible. We would also like to thank Facts and Comparisons for allowing us to use their data for the construction of some of our tables.

Two individuals from Lippincott Williams and Wilkins, Meredith Brittain and Loftin (Paul) Montgomery, Jr., deserve special recognition for their efforts. Their exceptional patience, attention to detail, and firm guidance helped us all stay on task. This edition would not have come to completion without their partnership. Mary Tod (copyediting), Ed Schultes, Jr. (multimedia production), and Jeri Litteral (typesetting) all played key roles in the production of the tenth edition, and we sincerely thank them for their assistance in completing this edition. Most importantly, we would be remiss not to acknowledge the love, understanding, and support of our spouses, children, and in some cases, grandchildren. They selflessly gave to us the many early mornings, late nights, and weekends we spent writing and editing.

As in past editions, we continue to dedicate our work to our students who inspire us and to the many patients we have been privileged to care for. Our patients have repeatedly taught us how critical it is to tailor our knowledge to their specific circumstances, to listen well, and to welcome them as true partners in their care.

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Additional Resources

The Tenth Edition of *Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs* includes additional resources for both instructors and students, available on the book's companion website at **http://thepoint.lww.com/AT10e.**

STUDENT RESOURCES

Students who have purchased *Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs,* Tenth Edition have access to the following additional resources for each chapter:

- An audio recording of that chapter's core principles
- A full online reference list for that chapter

In addition, at least one of the following supplements each chapter to enhance the chapter content:

- Audio files (most recorded by author)
- PowerPoints (most created by author)
- PowerPoints with audio (most created/recorded by author)
- Animations
- Videos (some created by author)
- Additional content (created by author)
- Interactive versions of the algorithms found in the book
- Full-color images

INSTRUCTOR RESOURCES

Approved adopting instructors will be given access to the following additional resources:

- PowerPoint slides
- Image bank (includes all images and tables in the book)
- Pathophysiology image collection

In addition, purchasers of the text can access the searchable Full Text On-line by going to the *Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs,* Tenth Edition website at **http://thepoint.lww.com/AT10e.** See the inside front cover for more details, including the passcode you will need to gain access to the website.

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1

Assessment of Therapy and Medication Therapy Management

Marilyn R. Stebbins, Timothy W. Cutler, and Patricia L. Parker

CORE PRINCIPLES

		CHAPTER CASES
1	Medication Therapy Management Services (MTMS) are provided to patients in all care settings but were first described in the Medicare Modernization Act of 2003.	**Case 1-5 (Questions 1, 5)**
2	MTMS includes comprehensive medication therapy review, developing a personalized medication record, a medication action plan, and documentation of the encounter.	**Case 1-5 (Questions 1–4)**
3	Medication reconciliation and taking an accurate and complete medication history are crucial to a successful MTMS encounter.	**Case 1-1 (Questions 1–3)**
4	Data necessary to perform MTMS can be obtained from many sources, including the patient, the paper chart, the pharmacy information system, and the electronic health record.	**Case 1-5 (Questions 1, 5)**
5	A careful and complete patient interview should include a medical, medication, and social history and must be provided in a culturally sensitive manner.	**Case 1-1 (Questions 1–3), Table 1-1, Online Content**
6	A successful MTMS encounter must be well documented following the Problem Oriented Medical Record.	**Case 1-5 (Question 1), Table 1-2**
7	The first step in documenting an MTMS encounter involves subjective and objective data collection to identify the primary problem.	**Case 1-2 (Question 1), Case 1-3 (Question 1), Case 1-4 (Question 1)**
8	Once the subjective and objective information is obtained, the clinician must assess the drug therapy or disease-specific problem. The assessment is the clinician's clinical justification for the plan.	**Case 1-5 (Questions 1, 2)**
9	The final step in documenting the MTMS encounter is developing the medication action plan and processing any billing requirements.	**Case 1-5 (Questions 1, 2, 4)**
10	To ensure the needs of the patient are met, communication of the plan with the patient and patient's other providers is required.	**Case 1-5 (Question 3)**

With the passage of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, pharmacists and other providers have tremendous opportunities in the implementation of health care reform.[1,2] One of the hallmarks of this law is delivery system reform. As health care delivery systems change, pharmacists have an opportunity to improve overall quality of care, to become involved in coordinated health care approaches such as medical home teams and accountable care organizations, and to collaborate to improve care for high-risk patients and those with chronic conditions in primary-care settings. Pharmacists practicing in acute care settings will have additional opportunities as hospitals will have

financial incentives to improve quality, reduce costs, and decrease hospital-acquired conditions.[1,2] With the pharmacists' expertise in medication therapy management, their leadership and involvement are crucial as these collaborative practices are being developed and implemented.

This chapter presents several approaches to assessing drug therapy and provides the framework for medication therapy management services (MTMS) across the continuum of care. The illustrations in this chapter primarily focus on the pharmacist; however, the principles used to assess patient response to drug therapy are of value to all health care providers.

MTMS was first described in the Medicare Modernization Act of 2003 (MMA 2003), which also established the first outpatient prescription drug benefit (also known as Medicare Part D) for those eligible for Medicare.[3] MTMS was defined in MMA 2003 as *a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure . . . that covered Part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.*

In 2003, the MMA defined eligibility criteria for MTMS, which were updated in 2010 to ensure that more Medicare beneficiaries would qualify for MTMS. MTMS-eligible beneficiaries must:

1. Take multiple Medicare Part D–covered drugs
2. Have multiple chronic diseases
3. Are likely to incur annual costs of at least $3,000 for all covered Part D drugs

Although MTMS is the term used in MMA 2003 to describe medication management for those eligible under the Medicare Part D benefit, the same approach is appropriate for any patient taking medications for chronic conditions. To respond to the need for further clarification of the term MTMS, 11 professional pharmacy associations more formally defined MTMS in a consensus document published in 2004.[4] According to this definition, MTMS can be applied to any patient in a variety of settings. Furthermore, this definition clarifies the type of activities involved in a medication therapy management (MTM) program.

MTMS has a direct relationship to pharmaceutical care. Pharmaceutical care has been described as *the responsible provision of drug therapy to achieve definite outcomes that are intended to improve a patient's quality of life.*[5,6] In fact, MTMS has been described as a service provided in the practice of pharmaceutical care.[7] However, unlike pharmaceutical care, MTMS is recognized by payers, has current procedural terminology (CPT) codes specifically for pharmacists, and has several clearly defined interventions. Therefore, MTMS will be the term used to describe the activity of MTM in various patient populations.

Both patient self-care and medication reconciliation are critical aspects of any MTMS encounter regardless of the setting (i.e., inpatient, community, ambulatory, or institutional). Patient self-care is defined by the World Health Organization as those *activities [that] individuals, families, and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health. These activities are derived from knowledge and skills from the pool of both professional and lay experience. They are undertaken by lay people on their own behalf, either separately or in participative collaboration with professionals.*[8] Patient self-care requires the patient to take responsibility for the illness; however, the help of a professional to structure healthy self-care is important. For example, patients with diabetes who monitor their blood glucose levels regularly and adjust their diet according to the guidelines published from the American Diabetes Association (ADA) would be practicing self-care. Self-care is often the work that the patient performs between visits with the provider. The patient should be involved in his or her own care to ensure the best outcomes.

Medication reconciliation is the comprehensive evaluation of a patient's medication regimen any time there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions, as well as to observe compliance and adherence patterns. This process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten or adjusted, or when the patient has added nonprescription medications to his or her self-care.[9] Although not a new concept to the profession of pharmacy, there has been heightened awareness and intensified effort in this area of practice as a result of the Joint Commission. The Joint Commission is the national accrediting body for hospitals and other health care delivery organizations that has committed to improving patient care through an inspection and evaluation process. In 2005, the Joint Commission announced its National Patient Safety Goal (NPSG) 8A and 8B to *accurately and completely reconcile medications across the continuum of care*. This goal requires institutions to develop and test processes for medication reconciliation in ambulatory and acute care settings.[10] Currently, the Joint Commission is re-evaluating and refining the standards surrounding NPSG 8 so that they can be more readily and successfully implemented by institutions. The release of the new standards is anticipated in January 2011.

The general approach to an MTMS patient encounter in various clinical settings will be discussed in the next sections. Figure 1-1 provides an overview of a patient encounter that includes information gathering from various data sources; interviewing the patient while using effective communication skills; assessing the medical illness(es); developing a plan to manage the illness(es); documenting the service (including billing); and monitoring, follow-up, or referral for any additional issues that cannot be resolved during the encounter.

SOURCES OF PATIENT INFORMATION

Successful patient assessment and monitoring requires the gathering and organization of all relevant information.[6,11] The patient (or family member or other representative) is always the primary source of information. The provider asks the patient a series of questions to obtain subjective information that is helpful in making a diagnosis or evaluating ongoing therapy. Likewise, pharmacists, home care nurses, and other providers without direct access to patient data also must obtain subjective data or measure objective physical data to guide recommendations for therapy and to monitor previously prescribed therapy.

Data-Rich Environment

In a "data-rich environment," such as a hospital, long-term care facility, or outpatient medical clinic, a wealth of information is available to practitioners from the medical record, pharmacy profile, and medication administration record (MAR). In these settings, physicians, nurses, and patients are readily available. This facilitates timely, effective communication among providers involved in the drug therapy decision-making process. Objective data (e.g., diagnosis, physical examination, laboratory and other test results, vital signs, weight, medications, medication allergies, intravenous flow rates, and fluid balance) are readily available. Likewise, the cases presented throughout this text usually provide considerable data on which to make more thorough assessments and therapeutic decisions. The patient record provides

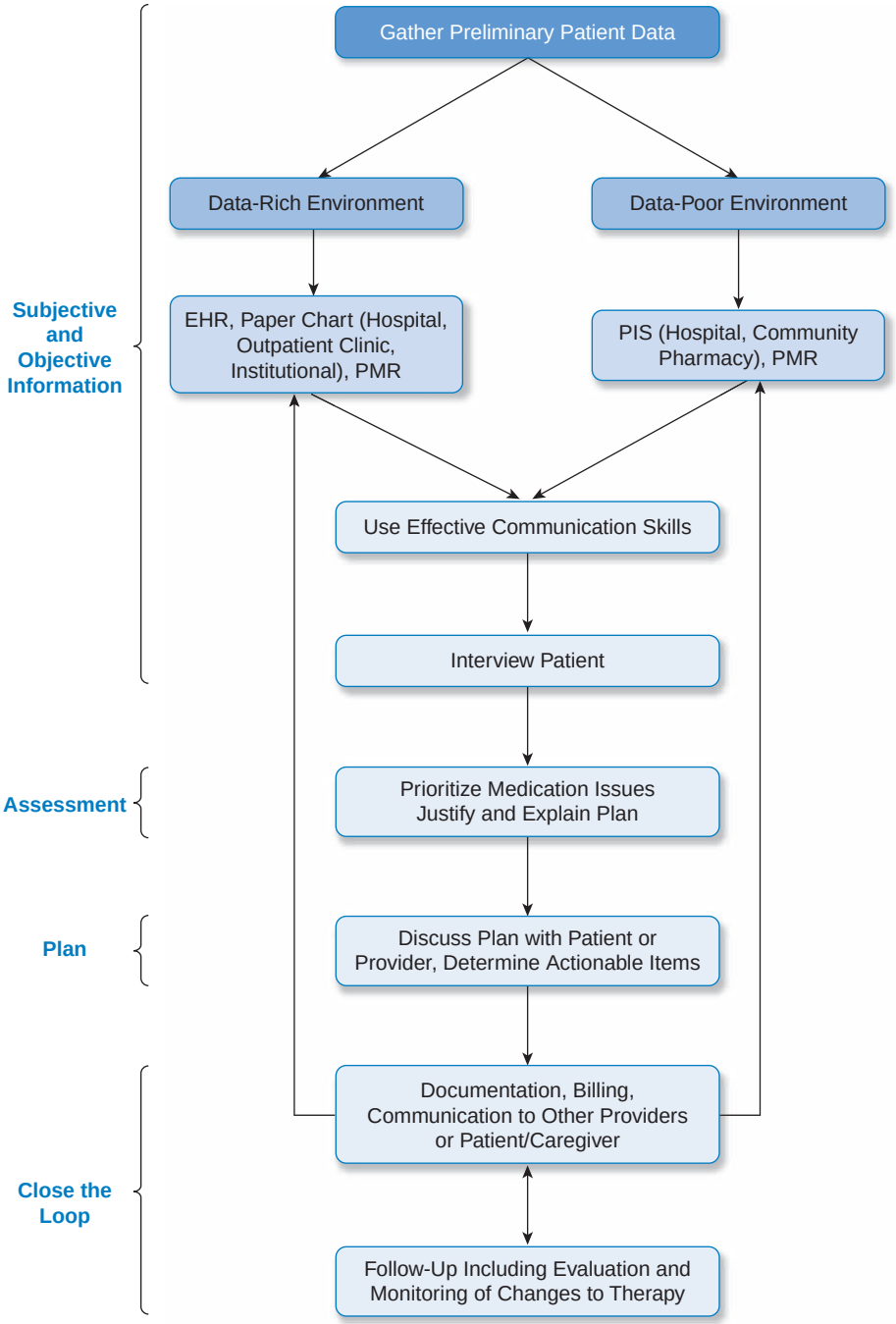

FIGURE 1-1 General approach to a patient encounter. EHR, electronic health record; PIS, pharmacy information system; PMR, personal medication record.

readily available information that is needed to identify and assess medical problems, which is necessary to design patient-specific care plans and document MTMS. In some settings, patient insurance information is important to help understand the formulary choices and access to medications.

PAPER CHARTS

A paper chart may be a source of valuable patient information. Paper charts may exist in a variety of settings, including the hospital, outpatient clinic, or institutional setting. This source of information is considered data rich but does have limitations. Paper charts are organized differently by site and by setting. The information contained in a hospital chart will be different from that contained in an outpatient clinic. Furthermore, it may be difficult to obtain a paper chart, or access may be delayed if another professional is using the chart. Significant data delays may occur in paper charts, as information such as laboratory results, test results, and chart notes may not be placed in the chart for several days after the test or documentation is complete. As a result, it is important to realize the limitations of this data-rich environment and that the information obtained during the patient interview is still extremely important.

ELECTRONIC HEALTH RECORD

An electronic health record (EHR) is an electronic version of the paper chart. These records are available in hospitals, clinics, and institutional settings, but the type of EHR and the organization of information will vary among the different settings and software applications. The EHR provides a wealth of information and is one of the most complete sources of reliable information. Unlike a paper chart, the EHR may be interfaced with the laboratory, pharmacy, and radiology systems so that data are available in real time with minimal delays. Unfortunately, clinicians may rely on the EHR too much for the patient information, and unless medication and problem lists are updated at every visit, this could lead to assumptions. For example, a patient who has metformin

500 mg twice daily listed in the EHR may actually be taking the medication once daily. Therefore, the data in the EHR are extremely useful, but it is still important to obtain information directly from the patient and to reconcile the medication and problem list and update the EHR accordingly.

Data-Poor Environment

In reality, clinicians are often required to make assessments with limited information. Even in a relatively data-poor environment, such as a community pharmacy, valuable sources of information are still available, including (a) the medication profile, (b) patient demographic data, (c) medication allergy history, and (d) the patient's insurance coverage information. In addition, it is often possible to consult with the prescriber (or the prescriber's office staff); however, contact may be delayed, and requests for information may be met with resistance owing to time constraints or other factors. As illustrated later in this chapter, the successful practitioner can make assessments and intervene on the patient's behalf even with limited information.

PHARMACY INFORMATION SYSTEMS

Pharmacy information systems (PIS) are generally considered data poor. When evaluating information available in PIS, it is important to the appreciate differences between inpatient and outpatient PIS. Pharmacy billing and inventory management were the motivation behind the establishment of the early PIS. These initial systems provided fill lists, generated patient profiles, and produced medication labels, which were valuable to institutional pharmacies as the profession moved toward a unit dose medication distribution system. More modern functionalities allow for some limited documentation of clinical pharmacy activities, but still, this system is data poor. Increased emphasis on patient safety highlights the importance of integrating PIS with other computerized systems used throughout the inpatient setting. An initiative set forth by the US Department of Health and Human Services, called the EHR Incentive Program, exemplifies the importance of the integration of systems.[12] This initiative, commonly referred to as the "Meaningful Use of an EHR," allows Medicare and Medicaid to provide incentive payments to providers and hospitals for the "meaningful use" of certified health information technology products. Eligibility for these incentive payments involves transitioning PIS to a more data-rich clinical information system (CIS), which includes direct computerized physician order entry, clinical decision support, an EHR, an electronic medication administration record (eMAR), and integration of various ancillary information systems such as pharmacy and laboratory services. Additional functionality incorporates the use of bar code technology, which allows the ability to track and promote quality assurance during the medication administration process. Information generated by the CIS is electronically transmitted to the pharmacy in real time, eliminating lost, illegible, or incomplete medication orders. Improved communication among various health care providers, decreased medication turnaround time, enhanced compliance with medication use policies and formularies, and reductions in medication errors are potential benefits of the EHR Incentive Program. Although increasing numbers of institutions are incorporating this technology into their practice settings, implementation of CIS in hospitals has not occurred for numerous reasons, including expense and system complexity.

Especially in a data-poor environment, it is important that the clinician be a proactive interviewer; in many instances, the interviewer becomes an investigator. The investigative approach is direct and requires strong problem-solving abilities and active listening skills. Questions should be formulated to obtain information such as the medication history, actual medication use, patient perception of care, use of over-the-counter (OTC) and natural or herbal products, and health beliefs (cultural or otherwise). This approach can help to verify and ensure the accuracy of other data sources. Clinicians should be mindful that not all patients are reliable historians, and some are poor sources of information. Even when the patient is a poor historian, the interview provides critical information (e.g., indicator of poor adherence, need for a caregiver or interpreter, etc.) that cannot be obtained from other sources.

EFFECTIVE COMMUNICATION AND THE PATIENT INTERVIEW

The ability to use effective communication principles and history-taking skills is crucial to a successful patient interaction.[6,11] The importance of interviewing the patient, how to set the stage for the interview, general interview rules, and the essential information to be obtained from the interview are outlined in Table 1-1.

TABLE 1-1
Interviewing the Patient

Importance of Interviewing the Patient

Establishes professional relationship with the patient to:
- Obtain subjective data on medical problems
- Obtain patient-specific information on drug efficacy and toxicity
- Assess the patient's knowledge about, attitudes toward, and pattern of medication use
- Formulate a problem list
- Formulate plans for medication teaching and pharmaceutical care

How to Set the Stage for the Interview
- Have the patient complete a written health and medication questionnaire, if available
- Introduce yourself
- Make the setting as private as possible
- Do not allow friends or relatives without permission of the patient
- Do not appear rushed
- Be polite
- Be attentive
- Maintain eye contact
- Listen more than you talk
- Be nonjudgmental
- Encourage the patient to be descriptive
- Clarify by restatement or patient demonstration (e.g., of a technique)

General Interview Rules
- Read the chart or patient profile first
- Ask for the patient's permission to conduct an interview or make an appointment to do so
- Begin with open-ended questions
- Move to close-ended questions
- Document interaction

Information to Be Obtained
- History of allergies
- History of adverse drug reactions
- Weight and height
- Drugs: dose, route, frequency, and reason for use
- Perceived efficacy of each drug
- Perceived side effects
- Adherence to prescribed drug regimen
- Nonprescription medication use (including complementary and alternative medications)
- Possibility of pregnancy in women of childbearing age
- Family or other support systems

Source: Teresa O'Sullivan, PharmD, University of Washington.

Information obtained from the patient is critical for assessment and planning in medication therapy management.

For an example of a patient interview and medication history taking tips, please go to http://thepoint.lww.com/AT10e.

OBTAINING A PATIENT HISTORY

Those who provide MTMS should develop standardized forms to record patient information obtained from the patient interview. Standardization facilitates quick retrieval of information, minimizes the inadvertent omission of data, and enhances the ability of other practitioners to use shared records.[6,11]

For convenience, the patient interview and record can be divided into sections with subjective and objective data as well as an assessment and plan (including expected outcomes). Components of subjective and objective data are the medical history, medication history, and social history. In some situations, these histories can be supplemented by the generation of flowchart diagrams to monitor changes in specific variables (e.g., blood glucose concentration, blood pressure, weight) with time. These charts and documentation systems may be incorporated into the EHR, PIS, or a similar electronic platform.

Medical History

The medical history is essential to the provision of MTMS. It can be as extensive as the medical records that are maintained in an institution or physician's office, or it can be a simple patient profile that is maintained in a community pharmacy. The purpose of the medical history is to identify significant past medical conditions or procedures; identify, characterize, and assess current acute and chronic medical conditions and symptoms; and gather all relevant health information that could influence drug selection or dosing (e.g., function of major organs such as the gastrointestinal tract, liver, and kidney, which are involved in the absorption and elimination of drugs; height and weight, including recent changes in either; age and sex; pregnancy and lactation status; and special nutritional needs). Not all interviews require the interviewer to ask for this much general information; however, in a data-poor environment, more information is required directly from the patient. A more focused interview may be appropriate in settings in which the information required is available electronically or is specific to a single disease state. For example, in an anticoagulation clinic, the information that is elicited from the patient is often specific to the patient's anticoagulation therapy (e.g., bleeding incidents, newly started medications, dietary changes, missed warfarin doses, etc.).

CASE 1-1

QUESTION 1: P.J., a 45-year-old woman of normal height and weight, states that she has diabetes. What questions might the practitioner ask of P.J. to determine whether type 1 or type 2 disease should be documented in her medical history?

Patients usually can enumerate their medical problems in a general way, but the practitioner often will have to probe more specifically to refine the diagnosis and assess the severity of the condition. Diabetes mellitus is used to illustrate the types of questions that can be used to gather important health information and assess drug therapy. The following questions should generate information that will help to determine whether P.J. has type 1 or type 2 diabetes mellitus.

- **How old were you when you were told you had diabetes?**
- **Do any of your relatives have diabetes mellitus? What do you know of their diabetes?**
- **Do you remember your symptoms? Please describe them to me.**
- **What medications have you used to treat your diabetes?**

When questions such as these are combined with knowledge of the pathophysiology of diabetes, appreciation of the typical presenting signs and symptoms of the disease, and understanding of the drugs generally used to treat both forms of diabetes, meaningful MTM can be provided. Even simple assessments such as the observation of a patient's body size can provide information useful for therapeutic interventions. For example, a person with type 2 diabetes is more likely to be an overweight adult (see Chapter 53, Diabetes Mellitus).

Medication History

In the community pharmacy setting, patients generally present themselves in one of four ways: (a) with a self-diagnosed condition for which nonprescription drug therapy is sought, (b) with a newly diagnosed condition for which a drug has been prescribed, (c) with a chronic condition that requires refill of a previously prescribed drug or the initiation of a new drug, or (d) on referral from their health plan or provider, or self-referral for focused medication therapy review (MTR). In the first and second situations, the practitioner must confirm the diagnosis by using disease-specific questions as illustrated in Question 1. In the third situation, the practitioner uses the same type of questioning as in the first two situations; however, this time the practitioner needs to evaluate whether the desired therapeutic outcomes have been achieved. The practitioner must evaluate the information gleaned during follow-up visits in the context of the history and incorporate it into his or her assessment and medication action plan (MAP). In the fourth situation, in which patients require a focused MTR, the medication and medical history information are equally important. Without the medical history, it is not possible to evaluate whether the drug therapy is appropriate, and without an accurate medication history, it is not possible to determine whether the patient has reached the desired goals of therapy for her condition. The goal of the medication history is to obtain and assess the following information: the specific prescription and nonprescription drugs that the patient is taking (the latter includes OTC medications, botanicals, dietary supplements, recreational drugs, alcohol, tobacco, and home remedies); the intended purpose or indications for each of these medications; how taken (e.g., route, ingestion in relation to meals), how much, and how often these medications are used; how long these agents have been taken or used (start and stop dates); whether the patient believes that any of these agents are providing therapeutic benefit; whether the patient is experiencing or has experienced any adverse effects that could be caused by each of these agents (idiosyncratic reactions, toxic effects, adverse effects); whether the patient has stopped taking any of the medications for any reason; and allergic reactions and any history of hypersensitivity or other severe reactions to drugs. This information should be as specific as possible, including a description of the reaction, the treatment, and the date of its occurrence.

The approach and process by which the medication history is obtained does not necessarily change based on the setting of the encounter. A successful medication reconciliation process consists of a standardized systematic approach, with the initial step

in this process involving the collection of the best medication history possible from every patient that enters any point in the health care system. The appropriate health care professional to obtain this information varies widely from one institution to the next, and may involve an array of individuals. Although pharmacists are uniquely qualified and have demonstrated increased accuracy in acquiring the medication history,[13] ultimately, medication reconciliation requires a multidisciplinary effort in which all available resources are integrated into each step of the process when appropriate.[14] Shared accountability by using key members of the health care team such as nurses, pharmacy technicians, pharmacists, and prescribers is essential in this process. Once an accurate medication history is obtained, this information is used to ensure that as the patient moves through the health care system, any deviation from prescribed regimen is deliberate and based on acute changes in the patient's condition. If an observed discrepancy is the result of an intended therapeutic decision by the prescribing clinician, appropriate documentation with either the reason for or intention to change, hold, or discontinue the medication should be completed in a manner that is clear to all members of the health care team. Unintentional variances in the medication lists should be considered as potential medication errors pending clarification from the prescribing clinician.

Because medication errors most commonly occur during transitions of care, the essential times to conduct medication reconciliation are when a patient is admitted to or discharged from a health care facility.[15,16] A crucial final step in the reconciliation process, and a vital piece of MTMS, occurs at discharge to avoid therapeutic duplication, drug interactions, and omissions of medications that may have been discontinued or placed on hold during hospitalization. On departure from a health care facility, a complete list of the patient's medications must be communicated to the patient and the next provider of service regardless of the setting. It is important to realize that efforts to implement a medication reconciliation process should not focus simply on fulfilling a Joint Commission standard but that this process allows for informed prescribing decisions and creates a safer environment for patients by improving the accuracy of medication administration throughout the continuum of care.

Perhaps the most important aspect of the medication history is to ensure that no assumptions related to medication use go unverified with the patient. The provider should ask questions related to how the current medication therapy is actually taken by the patient. The interviewer should then compare the use of medications as defined by the patient to the prescription information on the bottle or in the PIS/EHR. This information may identify discrepancies or misunderstandings between the prescriber and patient. As discussed previously, the patient may not have adequate health literacy, and the interpretation of the medication instructions printed on the bottle or described by a health professional may not be understandable to a patient. The review of the medication history is an opportune time to identify and clarify such misunderstandings.

CASE 1-1, QUESTION 2: P.J. has indicated that she is injecting insulin to treat her diabetes. What questions might be asked to evaluate P.J.'s use of and response to insulin?

The following types of questions, when asked of P.J., should provide the practitioner with information on P.J.'s understanding about the use of and response to insulin.

DRUG IDENTIFICATION AND USE

- **What type of insulin do you use?**
- **How many units of insulin do you use?**
- **When do you inject your insulin?**
- **Where do you inject your insulin? (Rather than the more judgmental question, "Do you rotate your injection sites?")**
- **Please show me how you usually prepare your insulin for injection. (This request of the patient requires the patient to demonstrate a skill.)**
- **What, if anything, keeps you from taking your insulin as prescribed?**

ASSESSMENT OF THERAPEUTIC RESPONSE

- **How do you know if your insulin is working?**
- **What blood glucose levels are you aiming for?**
- **What foods or meals do you find affect your blood sugars most?**
- **How often and when during the day do you test your blood glucose concentration?**
- **Do you have any blood glucose records that you could share with me?**
- **Please show me how you test your blood glucose concentration.**
- **What is your understanding of the hemoglobin A_{1c} blood test?**
- **When was the last time you had this test done?**
- **What were the results of the last hemoglobin A_{1c} test?**

ASSESSMENT OF ADVERSE EFFECTS

- **Do you ever experience reactions from low blood glucose?**
- **What symptoms warn you of such a reaction?**
- **When do these typically occur during the day?**
- **How often do they occur?**
- **What circumstances seem to make them occur more frequently?**
- **What do you do when you have a low blood glucose?**

The patient's responses to these questions on drug use, therapeutic response, and adverse effects will allow a quick assessment of the patient's knowledge of insulin and whether she is using it in a way that is likely to result in blood glucose concentrations that are neither too high nor too low. The responses to these questions also should provide the practitioner with insight about the extent to which the patient has been involved in establishing and monitoring therapeutic outcomes. Based on this information, the practitioner can begin to formulate the patient's therapeutic plan.

Social History

The social history is used to determine the patient's occupation and lifestyle; important family relationships or other support systems; any particular circumstances (e.g., a disability) or stresses in her life that could influence the MAP; and attitudes, values, and feelings about health, illness, and treatments.

CASE 1-1, QUESTION 3: A patient's occupation, lifestyle, insurance status, ability to pay, and attitudes often can determine the success or failure of drug therapy. Therefore, P.J.'s prescription drug coverage, nutritional history, her level of activity or exercise in a typical day or week, the family dynamics, and any particular stresses that may affect glucose control need to be documented and assessed. What questions might be asked of P.J. to gain this information?

WORK

- **Describe a typical workday and a typical weekend day.**

INSURANCE/COST

- **What type of prescription drug coverage do you have? How much do you pay for your insulin and diabetic supplies? How often do you go without your insulin or supplies because of their cost?**

EXERCISE

- **Describe your exercise habits. How often, how long, and when during the day do you exercise? Describe how you change your meals or insulin when you exercise.**

DIET

- **How many times per day do you usually eat? Describe your usual meal times.**
- **What do you usually eat for each of your main meals and snacks?**
- **Are you able to eat at the same time each day?**
- **What do you do if a meal is delayed or missed?**
- **Who cooks the meals at home? Does this person understand foods to prepare for someone with diabetes?**
- **How often do you eat meals in a restaurant?**
- **How do you order meals in a restaurant to maintain a proper diet for your diabetes? (*Note:* This is asked of patients who frequently dine in restaurants.)**

SUPPORT SYSTEMS

- **Who else lives with you? What do they know about diabetes? How do they respond to the fact that you have diabetes? How do they help you with your diabetes management? Does it ever strain your relationship? What are the issues that seem to be most troublesome? (*Note:* These questions apply equally to the workplace or school setting. Often, the biggest barrier to multiple daily injections is refusal of the patient to inject insulin while at work or school.)**

ATTITUDE

- **How do you feel about having diabetes?**
- **What worries or bothers you most about having diabetes? (*Note:* Participate in the patient's care. This approach is likely to enhance the patient–provider relationship, which should translate into improved care.)**

APPROACH TO AND ASSESSMENT OF PATIENT THERAPY

The provider–patient encounter will vary based on the location and type of services provided and access to necessary information. However, the general approach to the patient encounter should follow the problem-oriented medical record (POMR). Organizing information according to medical problems (e.g., diseases) helps to break down a complex situation (e.g., a patient with multiple medical problems requiring multiple drugs) into its individual parts.[4,5] The medical community has long used a *POMR* or *SOAP note* to record information in the medical record or chart by using a standardized format (Table 1-2). Each medical problem is identified, listed sequentially, and assigned a number. *Subjective* data and *objective* data in support of each problem are delineated, an *assessment* is made, and a *plan* of action identified. The first letter of the four key words (subjective, objective, assessment, and plan) serve as the basis for the SOAP acronym.

TABLE 1-2
Elements of the Problem-Oriented Medical Record[a]

Problem name: Each "problem" is listed separately and given an identifying number. Problems may be a patient complaint (e.g., headache), a laboratory abnormality (e.g., hypokalemia), or a specific disease name if prior diagnosis is known. When monitoring previously described drug therapy, more than one drug-related problem may be considered (e.g., nonadherence, a suspected adverse drug reaction or drug interaction, or an inappropriate dose). Under each problem name, the following information is identified:

Subjective	Information that explains or delineates the reason for the encounter. Information that the patient reports concerning symptoms, previous treatments, medications used, and adverse effects encountered. These are considered nonreproducible data because the information is based on the patient's interpretation and recall of past events.
Objective	Information from physical examination, laboratory test results, diagnostic tests, pill counts, and pharmacy patient profile information. Objective data are measurable and reproducible.
Assessment	A brief but complete description of the problem, including a conclusion or diagnosis that is supported logically by the above subjective and objective data. The assessment should not include a problem or diagnosis that is not defined above.
Plan	A detailed description of recommended or intended further workup (laboratory tests, radiology, consultation), treatment (e.g., continued observation, physiotherapy, diet, medications, surgery), patient education (self-care, goals of therapy, medication use and monitoring), monitoring, and follow-up relative to the above assessment.

[a] Sometimes referred to as the *SOAP* (subjective, objective, assessment, plan) note.

The POMR is a general approach and helps to focus the encounter, which provides a structure for the documentation of the services provided. The following section will describe the POMR and SOAP note in more detail.

Problem List

Problems are listed in order of importance and are supported by the subjective and objective evidence gathered during the patient encounter. Each problem in the list can then be given an identifying number. All subsequent references to a specific problem can be identified or referenced by that number (e.g., "problem 1" or simply "1"). These generally are thought of in terms of a diagnosed disease, but they also may be a symptom complex that is being evaluated, a preventive measure (e.g., immunization, contraception), or a cognitive problem (e.g., nonadherence). Any condition that requires a unique management plan should be identified as a problem to serve as a reminder to the practitioner that treatment is needed for that problem. Different settings and activities or clinical services will determine the priority of the problems identified.

Medical problems can be *drug related*, including prescribing errors, dosing errors, adverse drug effects, adherence issues, and the need for medication counseling. Drug-related problems may be definite (i.e., there is no question that the problem exists) or possible (i.e., further investigation is required to establish whether the problem really exists). The most commonly encountered types of drug-related problems are listed in Table 1-3.[6,11]

TABLE 1-3
Drug-Related Problems

Drug Needed
Drug indicated but not prescribed; a medical problem has been diagnosed, but there is no indication that treatment has been initiated (maybe it is not needed)
Correct drug prescribed but not taken (nonadherence)

Wrong or Inappropriate Drug
No apparent medical problem justifying the use of the drug
Drug not indicated for the medical problem for which it has been prescribed
Medical problem no longer exists
Duplication of other therapy
Less expensive alternative available
Drug not covered by formulary
Failure to account for pregnancy status, age of patient, or other contraindications
Incorrect nonprescription medication self-prescribed by the patient
Recreational drug use

Wrong Dose
Prescribed dose too high (includes adjustments for renal and hepatic function, age, body size)
Correct prescribed dose but overuse by patient (overadherence)
Prescribed dose too low (includes adjustments for age, body size)
Correct prescribed dose but underuse by patient (underadherence)
Incorrect, inconvenient, or less-than-optimal dosing interval (consider use of sustained-release dosage forms)

Adverse Drug Reaction
Hypersensitivity reaction
Idiosyncratic reaction
Drug-induced disease
Drug-induced laboratory change

Drug Interaction
Drug–drug interaction
Drug–food interaction
Drug–laboratory test interaction
Drug–disease interaction

The distinction between medical problems and drug-related problems sometimes is unclear, and considerable overlap exists. For example, a medical problem (i.e., a disease, syndrome, symptom, or health condition) can be prevented, cured, alleviated, or exacerbated by medications. When assessing drug therapy, several situations could exist: treatment is appropriate and therapeutic outcomes have been achieved; drugs that have been selected are ineffective or therapeutic outcomes are partially achieved; dosages are subtherapeutic or medication is taken improperly; an inappropriate drug for the medical condition being treated has been prescribed or is being used; or the condition is not being treated.

Likewise, a drug-related problem can cause or aggravate a medical problem. Such drug-related problems could include hypersensitivity reactions; idiosyncratic reactions; toxic reactions secondary to excessive doses; adverse reactions (e.g., insulin-induced hypoglycemia or weight gain); drug–drug, drug–disease, drug–laboratory test, and drug–lifestyle interactions; or polypharmacy (using multiple medications), which may increase the risk of adverse drug events.[17]

Subjective and Objective Data

Subjective and objective data in support of a problem are important because assessment of patients and therapies requires the gathering of specific information to verify that a problem continues to exist or that therapeutic objectives are being achieved. Subjective data refer to information provided by the patient or another person that cannot be confirmed independently. This is the data most commonly obtained during a patient interview. Objective data refer to information observed or measured by the practitioner (e.g., laboratory tests, blood pressure [BP] measurements). The objective data are most commonly obtained from the EMR or paper chart (data-rich environment). However, some objective data can be obtained in data-poor environments. In the absence of a medical record, weight, height, pulse, BP, blood glucose readings, and other objective information can be gathered during the provider–patient encounter.

CASE 1-2

QUESTION 1: P.N., a 28-year-old man, has a BP of 140/100 mm Hg. What is the primary problem? What subjective and objective data support the problem, and what additional subjective and objective data are not provided but usually are needed to define this particular problem?

The primary problem is hypertension. No subjective data are given. The objective data are the patient's age, sex, and BP of 140/100 mm Hg. Each of these is important in designing a patient-specific therapy plan. Because hypertension often is an asymptomatic disease (see Chapter 14, Essential Hypertension), subjective complaints such as headache, tiredness or anxiety, shortness of breath (SOB), chest pain, and visual changes usually are absent. If long-term complications such as rupturing of blood vessels in the eye, glomerular damage, or encephalopathy were present, subjective complaints might be blurring or loss of vision, fatigue, or confusion. Objective data would include a report by the physician on the findings of the chest examination (abnormal heart or lung sounds if secondary heart failure [HF] has developed), an ocular examination (e.g., presence of retinal hemorrhages), and laboratory data on renal function (blood urea nitrogen, creatinine, or creatinine clearance). To place these complications in better perspective, the rate of change should be stated. For example, the serum creatinine has increased from a level of 1 mg/dL 6 months ago to a value of 3 mg/dL today. Vague descriptions such as "eye changes" or "kidney damage" are of little value, because progressive damage to these end organs results from uncontrolled high BP, and disease progression needs to be monitored more precisely.

CASE 1-3

QUESTION 1: D.L., a 36-year-old construction worker, tripped on a board at the construction site 2 days ago, sustaining an abrasion of his left shin. He presents to the emergency department with pain, redness, and swelling in the area of the injury. He is diagnosed as having cellulitis. What is the primary problem? What subjective and objective data support the problem? What additional subjective and objective data are not provided but usually are needed to define this particular problem?

The primary problem is cellulitis of the left leg. Useful pieces of subjective information are D.L.'s description of how he injured his shin at a construction site and his current complaints of pain, redness, and swelling. The fact that he was at a construction site is indirect evidence of a possible dirty wound. Further information must be obtained about how he cleaned the wound after the injury and whether he has received a booster dose of tetanus toxoid within the past 10 years. Objectively, the wound is on the left shin. No other objective data are given. Additional data to obtain would be to document the intensity of the redness on a one-to-four-plus scale, the size of the inflamed area as

described by an area of demarcation, the circumference of his left shin compared with his right shin, the presence or absence of pus and any lymphatic involvement, his temperature, and a white blood cell count with differential.

CASE 1-4

QUESTION 1: C.S., a 58-year-old woman, has had complaints of fatigue, ankle swelling, and SOB, especially when lying down, for the past week. Physical examination shows distended neck veins, bilateral rales, an S_3 gallop rhythm, and lower extremity edema. A chest radiograph shows an enlarged heart. She is diagnosed as having HF and is being treated with furosemide and digoxin. What is/are the primary problem(s)? What subjective and objective data support the problem(s)? What additional subjective and objective data are not provided but usually are needed to define this (these) particular problem(s)?

The primary problem is systolic HF. Subjectively, C.S. claims to be experiencing fatigue, ankle swelling, and SOB, especially when lying down. She claims to have been taking furosemide and digoxin. An expanded description of these symptoms and her medication use would be helpful. The findings on physical examination and the enlarged heart on chest radiograph are objective data in support of the primary problem of HF. In addition, other objective findings that would help in her assessment would be the pulse rate, BP, serum creatinine, serum potassium concentration, digoxin blood level, a more thorough description of the rales on lung examination, extent of neck vein distension, and degree of leg edema. Pharmacy records could be screened to determine current dosages and refill patterns of the medications.

In this case, a second primary problem may be present. Current recommendations for the management of HF include use of an angiotensin-converting enzyme (ACE) inhibitor before or concurrent with digoxin therapy. Thus, a possible drug-related problem is the inappropriate choice of drug therapy ("wrong drug"). The patient or prescriber should be consulted to ascertain whether an ACE inhibitor has been used previously, any contraindications exist, or possible adverse effects were encountered.

Assessment

After the subjective and objective data have been gathered in support of specific listed problems, the practitioner should assess the acuity, severity, and importance of these problems. He or she should then identify all factors that could be causing or contributing to the problem. The assessment of the severity and acuity is important because the patient expects relief from the symptoms that are of particular concern at this time. During the initial encounter with a patient, it might be discovered that the medical problem is only a symptom complex and that a diagnosis is needed to more accurately identify the problem and further define its severity.

The assessment is usually performed during or immediately after the data gathering while the provider keeps in mind evidence-based practices. For example, if diabetes is assessed and pertinent subjective data (medication history, social history, diet, and exercise, etc.) and objective data exist (laboratory test results like hemoglobin A_{1c}, low-density lipoprotein cholesterol [LDL-C], BP, etc.), then the assessment of diabetes may be to determine whether the patient is meeting the goals for the disease as defined by the ADA. If the patient is not at goal, then the explanation of the reasons why would be described in the assessment, and the plan would then be centered on helping that patient get to goal. Sometimes, the distinction between subjective information provided by the patient and assessments made by the practitioner are confused in the POMR. What the patient reveals belongs in the subjective data, and how the provider interprets it belongs in the assessment. For example, a patient stating that she is having difficulty affording her medications belongs in the subjective information. However, a patient appearing to have cost-related nonadherence belongs in the assessment, as it is the provider's interpretation of what the patient has stated.

DRUG THERAPY ASSESSMENT

A responsibility of the practitioner is to monitor the response of patients to prescribed therapeutic regimens. The purpose of drug therapy monitoring is to identify and solve drug-related problems and to ensure that all therapeutic objectives are being achieved. Unless proven otherwise, the medical diagnosis should be assumed to be correct. On occasion, the diagnosis may not be readily apparent, or a drug-induced problem may have been diagnosed incorrectly as being a disease entity.

Nurses, pharmacists, physicians, physician assistants, and other health care practitioners share the responsibility to assess and monitor patient drug therapy. For the pharmacist, medication reconciliation and the drug therapy assessment may occur in many practice settings, including the community pharmacy while dispensing or refilling prescriptions or counseling patients, during MTMS encounters in the home or in the clinic, while assessing therapy for the hospitalized patient, or as part of routine monthly evaluations of patients residing in long-term care facilities. Many states have enacted legislation allowing pharmacists to develop collaborative drug therapy agreements with physicians for disease state management of common disorders such as asthma, diabetes, dyslipidemia, and hypertension. Additional services commonly provided by pharmacists through collaborative drug therapy agreements include anticoagulation monitoring, emergency contraception, and immunizations.[7] These services often involve more detailed drug therapy evaluation and assessment and may occur within or outside the traditional pharmacy setting. Regardless, the patient's need (this should be the primary consideration), time constraints, working environment (a determinant of the amount of patient information that is available), and practitioner's skill level govern the extent of monitoring. Similarly, the exact steps used to monitor therapy and the order in which they are executed need to be adapted to a practitioner's personal style. Thus, the examples given in this chapter should be used by the reader as a guide rather than as a recipe in a cookbook.

Plan

After the problem list is generated, subjective and objective data are reviewed, and the severity and acuity of the problems are assessed and prioritized, the next step in the problem-oriented (i.e., SOAP) approach is to create a plan, which at the minimum should consist of a diagnostic plan and an MAP that includes patient education. The plan is the action that was justified in the assessment. The plan is clear and direct and does not require explanation (this should be explained in the assessment). For example, if a patient is experiencing constipation while taking an opioid pain reliever, the plan would be to recommend a stool softener and stimulant laxative such as docusate sodium and bisacodyl. The plan should also include any follow-up that would be necessary as a result of to the action taken.

Patient Education

Educating patients to better understand their medical problem(s) and treatment is an implied goal of all treatment plans. This

process is categorized as the development of a patient education plan. The level of teaching has to be tailored to the patient's needs, health literacy, willingness to learn, and general state of health and mind. The patient should be taught the knowledge and skills needed to achieve and evaluate his or her therapeutic outcome. An important component of the patient education plan emphasizes the need for patients to follow prescribed treatment regimens.

The POMR will allow the provider to focus the interview and encounter independent of the site or service offered. The POMR facilitates documentation of the provision of MTMS across multiple sites and services (across the continuum of care).

The next few sections will discuss how to approach MTMS in various clinical settings.

MEDICATION THERAPY MANAGEMENT SERVICES IN THE COMMUNITY PHARMACY OR AMBULATORY SETTING

The core elements of MTMS have been described by the American Pharmacists Association (APhA) and the National Association of Chain Drug Stores.[18] According to these organizations, the core elements of MTMS should include the following components:

1. Medication therapy review (MTR)
2. Personal medication record (PMR)
3. Medication action plan (MAP)
4. Intervention or referral
5. Documentation and follow-up

Medication Therapy Review (MTR)

The MTR may be a comprehensive review, including medication reconciliation, in which the provider reviews all of the medications the patient is currently taking, or it may be a focused review of one medication-related issue such as an adverse event. Examples of services provided during the MTR are described in Table 1-4. MTR is dependent on the information that is available from the patient or other data sources. Community pharmacies may be a data-poor environment, and access to necessary information may be limited. In some ambulatory clinics, the provider may have access to the EHR (data-rich environment).

TABLE 1-4
Examples of Services Provided During a Medication Therapy Review

- Assess the patient's health status
- Assess cultural issues, health literacy, language barriers, financial status, and insurance coverage or other patient characteristics that may affect the patient's ability to take medications appropriately
- Interview the patient or caregiver to assess, identify, and resolve actual or potential adverse medication events, therapeutic duplications, untreated conditions or diseases, medication adherence issues, and medication cost considerations
- Monitor medication therapy, including response to therapy, safety, and effectiveness
- Monitor, interpret, and assess patient laboratory values, especially as they relate to medication use/misuse
- Provide education and training on the appropriate use of medications
- Communicate appropriate information to other health professionals, including the use and selection of medication therapy

Source: American Pharmacists Association; National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). *J Am Pharm Assoc (2003).* 2008;48(3):341–353.

Personalized Medication Record (PMR)

Regardless of the setting, a necessary tool to help with the gathering of the medication information is the PMR. This medication record should be updated after any change in medication therapy and should be shared with other health care providers. The patient is responsible for the upkeep of the PMR, but the PMR requires periodic review by the pharmacist or other provider. The goal of this record is to promote self-care and ownership of the medication regimen.[18] The PMR should be used at all levels of care, thereby facilitating the medication reconciliation process required across the continuum of care. An example of a PMR is shown in Figure 1-2.

Once the patient interview has occurred and the PMR has been updated, the provider may still require information to make an assessment. In such cases, the provider must do his or her best with the available information, or may obtain missing information such as the medical history or objective data from other providers. Lack of objective information is common in the community pharmacy setting, and the ability to address all problems effectively may be limited in this data-poor environment. In some encounters, obtaining the necessary information and medication reconciliation may take the entire visit, necessitating a follow-up encounter.

Medication Action Plan (MAP)

If adequate information is available to assess the current problem, an MAP should be developed. Because the MAP is patient centered and is prioritized according to the urgency of need, the provider and the patient should develop the plan together. An example of an MAP can be seen in Figure 1-3.

Intervention and Referral

The MAP often describes the intervention performed in an MTM encounter and may serve as documentation that can be shared with the patient and other health care providers (like the PMR). The primary purpose of the MAP is to make the action plan patient centered and to provide the patient with documentation of what they need to do next in the action plan. It also provides space for the patient to document what he or she did related to this action and when it was done. In some instances, the MAP may involve referral to another provider (a physician or pharmacist with additional qualifications) if the issue is beyond the scope of the intervening pharmacist. Some reasons for referral may include diabetes education by a certified diabetes educator, diagnosis of a new or suspected medical condition, or laboratory testing that may be beyond the scope of the pharmacist.

Coordination of care is a key element of MTMS and MTR.[4] This may include improving the communication between the patient and other health care providers, enhancing the patient's understanding of his or her health issues or concerns, maximizing health insurance coverage, advocating on behalf of the patient to get needed medications using available resources and programs, and various other functions that will improve the patient's understanding of his or her health care environment and promote self-care. Coordination of care may be the primary action taken on behalf of the patient and may be included in the MAP.

Patient: M.C. ALLERGIES: None Type of reaction: N/A	Primary Physician: Dr. Sara Smith (555-3971)	Pharmacist: Mary Doe (555-5551)	Date Prepared: 4/2/12	Date Updated: 5/2/12

Start Date	Medication (generic)	Dosage	Route	Times per Day	Scheduled Times	Purpose for Use	Remarks	Prescriber (Phone)	Stop Date
1/2/12	(lisinopril)	40 mg	By mouth	Once	9 a.m.	High blood pressure		Sara Smith, MD (555-3971)	
1/2/12	(metoprolol)	50 mg	By mouth	Twice	9 a.m. and 9 p.m.	High blood pressure		Sara Smith, MD (555-3971)	
1/2/12	(glipizide)	5 mg	By mouth	Once	9 a.m.	Diabetes	Take 30 minutes before breakfast	Sara Smith, MD (555-3971)	
1/2/12	(indomethacin)	50 mg	By mouth	Up to three times if needed	9 a.m., 4 p.m., 11 p.m.	Back pain	Take with food. Do not take this medicine with other anti-inflammatory medicines (e.g., ibuprofen, naproxen). Do not take this medication unless you have pain.	Sara Smith, MD (555-3971)	
4/2/12	Crestor® (rosuvastatin)	40 mg	By mouth	Once	9 a.m.	Cholesterol		Ted Hart, MD (555-1234)	

Bring this Personal Medication Record with you to all visits with health care providers and if you are admitted to a hospital. Contact your pharmacist regarding questions or updates.

FIGURE 1-2 Example of a Personal Medication Record (PMR).

Documentation and Follow-up

The development of a documentation process is a necessary component of MTMS.[18] Documentation should be standardized and based on the POMR format. All appropriate records, including the PMR and MAP, should be shared with other providers to promote communication and continuity of care. If the encounter requires follow-up, the documentation should reflect the timing of the follow-up care, and any expectations of the patient and providers should be included. Thorough documentation of the encounter allows all providers to quickly assess the progress of the patient and determine that the desired outcome has been achieved.

My Medication–Related Action Plan

Patient:	M.C.
Provider (Phone):	Dr. Sara Smith (555-3971)
Pharmacy/Pharmacist (Phone):	RiteMart/Mary Doe, PharmD (555-5551)
Date Prepared:	May 2, 2012

The list below has important Action Steps to help you get the most from your medications. Follow the checklist to help you work with your pharmacist and providers to manage your medications AND make notes of your actions next to each item on your list

Action Steps → What I need to do...	Notes → What I did when I did it...
☐ **For your muscle weakness and soreness** Stop Crestor® (rosuvastatin) 40 mg. We asked Dr. Hart to change to a lower dose or different agent such as simvastatin. Obtain blood test from Dr. Hart's office. Follow-up with Dr. Hart in 2 days.	
☐ **Medicine Cost** We have asked Dr. Hart to stop Crestor (rosuvastatin) as it is too expensive. A generic medicine such as simvastatin will cost you less and was recommended to Dr. Hart as an alternative. Continue to ask your pharmacist and doctor whether the medications you are taking are covered by your Medicare Part D plan and whether there are any alternatives that might be less expensive for you.	
☐ **For Pain** Talk to Dr. Sara Smith about other pain medicines because the indomethacin may not be the best choice for you because of side effects. Some choices might include other medicines such as Vicodin (hydrocodone and acetaminophen), over-the-counter acetaminophen, or medicines like naproxen or ibuprofen.	

My next appointment with my pharmacist is on: _____ **(date) at** _____ ☐**AM** ☐**PM**

This form is based on forms developed by the American Pharmacist Association and the National Association of Chain Drug Store Foundation. Reproduced with permission from APhA and NACDS Foundation.

FIGURE 1-3 Example of a Medication Action Plan (MAP).

An important aspect of documenting the encounter is to submit billing for the encounter when appropriate. Although billing for MTMS is not universally accepted by all payers, the introduction of the national provider identifier (NPI) and pharmacist-specific CPT codes may soon make this a reality.[7,19] The implementation of Medicare Part D in 2006 allowed pharmacists in pharmacies contracted with prescription drug plans to provide MTMS to plan-identified Medicare recipients. Pharmacists bill these plans through the contracted pharmacy by using an NPI and one of three CPT codes. The NPI number designates the provider to be paid, and the CPT determines the amount of payment based on the services rendered. The CPT codes specific to pharmacists providing MTMS include the following:

CPT 99605: Initial face-to-face assessment or intervention by a pharmacist with the patient for 1 to 15 minutes
CPT 99606: Subsequent face-to-face assessment or intervention by a pharmacist with the patient for 1 to 15 minutes
CPT 99607: Each additional 15 minutes spent face-to-face by a pharmacist with the patient; used in addition to 99605 or 99606

Although the NPI number and CPT codes allow pharmacists to bill for MTMS, the reimbursement varies by plan and negotiated contract and is beyond the scope of this text. Pharmacists have also developed patient self-pay reimbursement strategies as well as contracts with self-insured employers and state-run Medicaid programs to provide services.[20,21]

The Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010 describe the need for payment reform that promotes improved quality of care. Other providers also see these laws providing new opportunities for pharmacists to participate in care teams such as the patient-centered medical home and pay-for-performance programs to improve medication-related care coordination, quality scores, and patient outcomes.[22,23] The enhanced payment for improving quality in medication-related areas could be used to fund the pharmacist in this activity.

CASE 1-5

QUESTION 1: M.C. is a 76-year-old woman who comes to an appointment at the community pharmacy with her daughter for a focused MTR. She has a Medicare Part D prescription drug plan and is asking for help with her medication costs. She indicates that she has type 2 diabetes, hypertension, back pain, and hyperlipidemia. Her medications include lisinopril 40 mg once daily, metoprolol 50 mg twice daily, glipizide 5 mg once daily, indomethacin 50 mg up to three times daily as needed for pain, and rosuvastatin 40 mg once daily. M.C. tells you that she has trouble paying for her rosuvastatin (tier 3, $60 copayment) and would rather have something generic that costs less (tier 1, $5 copayment). Further, she complains of muscle soreness and weakness during the last 3 weeks. What objective information can be obtained in a community pharmacy setting? What is the primary problem? What additional information is necessary to determine the cause of her problem? How would a clinician assess and document her problem(s) in a SOAP format?

Although generally not considered a data-rich environment, increasing amounts of objective information can be gathered during the patient encounter at a community pharmacy. Specifically, information such as weight, BP, temperature, and finger-stick glucose and cholesterol levels can be measured if indicated for this patient. This information may be useful to the community pharmacist when performing the MTR to determine whether the medications are achieving the desired therapeutic outcomes. Although the patient presented for MTR, the primary complaint is the patient's self-reported muscle weakness and soreness during the last 3 weeks. Assuming that M.C. is a patient of this pharmacy, the practitioner could gather the necessary medication history from the PIS. Because the patient is present, this is a good opportunity to develop a PMR with M.C. While developing the PMR with the patient, the practitioner should gather additional information from M.C. about her medication use. For example, the name of one of M.C.'s medicines could be read with the practitioner continuing to ask open-ended questions such as, "How do you take this medication?" "What is your routine for taking your medication?" and "What types of problems, if any, have you had while using this medication?" This process will help to quickly identify any medication discrepancies between the pharmacy computer system and the patient's understanding of medication administration. If discrepancies are noted, the practitioner can clarify them with M.C. right away as part of the intervention. The PMR should also include a section to list medication allergies. The type of reaction should also be included on the PMR so that other providers will know the severity of the medication allergy (i.e., intolerance vs. anaphylactic reaction). Based on data gathered from the pharmacy computer and M.C., a PMR (depicted in Fig. 1-3) could be developed.

Reviewing the medications alone often does not provide enough information to determine whether M.C. is experiencing a medication-related event. Further questioning may be necessary. M.C. should be asked questions such as "What other medications have you tried in the past?" "How often do you experience muscle weakness and soreness?" "Which muscles are hurting?" "Show me where the problem is," "What do you think is causing the problem?" or "Describe the problem you are experiencing in more detail." Asking questions related to the onset of her symptoms of muscle soreness and weakness will help to determine whether this is a medication-related problem.

The practitioner can develop an assessment from this questioning and the PMR of the current problem that she is experiencing. As indicated on the PMR, M.C. started rosuvastatin most recently. The initiation of this medication corresponds to the onset of her recent soreness and weakness. β-Hydroxy-β-methylglutaryl-CoA (HMG-CoA) reductase inhibitors like rosuvastatin are known to cause myositis, or muscle breakdown, which may lead to weakness and muscle soreness. Furthermore, the prescribed dose is high for a woman of M.C.'s age. Based on this information, an assessment of the problem can be pursued. If rosuvastatin is the suspected agent, the plan would include actions necessary to solve the problem or to determine whether rosuvastatin is the cause of her muscle soreness and weakness. Unfortunately, not all of the necessary information is available (e.g., her baseline cholesterol, serum creatinine, liver function tests, or creatine kinase levels) to develop a formal plan of action to resolve the adverse medication event. However, part of the plan may be to obtain the laboratory test results necessary to identify or act on the adverse medication event. An example of the documentation of the SOAP note follows.

PRIMARY PROBLEM:
Muscle soreness and weakness (possible adverse medication event)
SUBJECTIVE:
M.C. reports weakness and soreness, predominantly in her legs during the past 3 weeks. She has difficulty rising from her chair after sitting for long periods and describes the pain as aching. The patient reports taking her medications as prescribed and rarely misses a dose.
OBJECTIVE:
Total Cholesterol: 137 mg/dL; LDL-C: 56 mg/dL; HDL: 54 mg/dL; Triglycerides: 136 mg/dL
Temperature: 98.5°F

ASSESSMENT:

M.C. has muscle weakness and soreness in her large muscle groups. She is currently at the recommended LDL-C goal level for a person with diabetes and hypertension per NCEP ATP III guidelines (very-high-risk LDL-C goal is <70 mg/dL).[24] Her current lipid therapy is rosuvastatin 40 mg once daily, which was started by her cardiologist 6 weeks ago. The initiation of rosuvastatin 40 mg correlates to the timing of her muscle soreness and weakness. HMG-CoA reductase inhibitors (i.e., rosuvastatin) are known to cause myositis or myalgias, and this patient is at particular risk given her age, sex, and starting dose. It is possible that the rosuvastatin could be causing her muscle soreness and weakness. Other lipid-lowering agents could be tried or the dose of rosuvastatin could be reduced, which might eliminate or reduce this adverse event. A creatine kinase level should be obtained to determine the severity of the myositis. A serum creatinine should also be measured, as myositis can lead to renal damage and rhabdomyolysis in severe cases; however, this is usually accompanied by fever and other symptoms that the patient is not currently experiencing.

PLAN:

1. **DRUG-RELATED ADVERSE EVENT:**
   - Discussed the possibility of an adverse medication event with the patient, which included the signs and symptoms of myalgias and myositis.
   - Contacted Dr. Hart (M.C.'s cardiologist) to discuss the current problem with rosuvastatin.
   - Per discussion with Dr. Hart, will obtain a creatine kinase level and serum creatinine.
   - Discontinue rosuvastatin per the pharmacist's recommendation. Dr. Hart agreed that M.C. should temporarily stop her rosuvastatin until her laboratory values are reviewed.
   - Alternative dosing of rosuvastatin 5 mg or another equivalent agent (atorvastatin 10 mg or simvastatin 20 mg) was discussed with Dr. Hart.
   - M.C. is to see Dr. Hart in the cardiology clinic in 2 days to discuss the laboratory values and alternative therapies.
   - Discussed the entire plan with M.C., and she verbalized understanding of steps that she is to take with respect to her current medication-induced problem.

CASE 1-5, QUESTION 2: From M.C.'s medication profile, what other problems can be identified with her medication therapy? What can be done to address these issues?

There are three remaining issues that may need to be addressed. The first issue relates to the pain medicine (indomethacin) that M.C. is taking. It is suggested that indomethacin may have a higher rate of central nervous system side effects in the elderly compared with other agents in the same class.[25] Furthermore, the American Geriatric Society guidelines on the management of mild to moderate persistent pain caution the use of nonsteroidal anti-inflammatory agents in older adults, preferring acetaminophen as a first-line agent.[26] Other prescription medications such as hydrocodone/acetaminophen or nonprescription medication such as acetaminophen alone could be used to help treat M.C.'s pain (see Chapter 7, Pain and Its Management, and Chapter 102, Geriatric Drug Use). Second, it is not clear from the current information whether the various providers are communicating. It is the responsibility of the pharmacist to help coordinate care among multiple prescribers as described by the APhA MTMS consensus document.[4] Therefore, it is important to be sure that both providers (Drs. Smith and Hart) receive a copy of the documentation of the issues addressed during the visit (SOAP note).

Finally, M.C. came into the pharmacy asking for help with her medication costs. To assess this problem, it is important to ask whether there are specific cost issues with a particular drug or whether it is her overall medication regimen that causes her concern. Another important question to ask is whether she has stopped taking any medications or changed the way that she takes her medications because of cost. Many patients will discuss cost and adherence issues with their pharmacist, because the point of sale for medications occurs at the pharmacy. However, they may not discuss this problem with the prescriber. Cost and nonadherence due to cost may be medication-related problems that the pharmacist must communicate to the prescriber on behalf of the patient. In assessing drug cost, there are several steps that can be taken. First, determine the patient's ability to pay for medications; implement low-cost, medically appropriate interventions targeted to patient needs; facilitate enrollment into relevant benefit programs; and confirm medication changes with the patient and prescribers (Table 1-5).

TABLE 1-5
Cost Containment Strategies

Patient With Prescription Drug Coverage
- Maximize generic drugs
- Maximize formulary coverage
- Switch to agents covered on the least expensive formulary tier
- If patient has Medicare Part D, determine eligibility for low-income subsidy through the Social Security Administration
- Consider mail-order prescription programs

Uninsured Patient
- Use low-cost generic programs (e.g., Rx Outreach, Costco, Wal-Mart, Target generic programs)
- Switch to therapeutically equivalent lower-cost brand name drugs when generics are unavailable
- Consider tablet splitting, if appropriate
- Consider pharmaceutical industry–sponsored patient assistance programs or foundation-sponsored copay-assistance programs
- Determine whether the patient is eligible for Medicaid, Medicare, Medicare Part D, or other assistance programs

For M.C., the rosuvastatin is her biggest concern, as it costs $60 per month and her Medicare Part D plan lists it as a nonpreferred (tier 3) agent on the formulary. With the possible discontinuation of her rosuvastatin, it is important for the pharmacist to anticipate her need for an alternative lipid-lowering agent and to determine whether there are cost-effective formulary alternatives that may be appropriate. This information can then be relayed to the prescriber. Furthermore, the alternative lipid-lowering formulary choice can be integrated into the plan developed for the primary issue of muscle soreness and weakness (see Case 1-5, Question 1). The integration of multiple problems is a complicated but important aspect of the MAP.

CASE 1-5, QUESTION 3: What additional information can be provided to M.C. at this time?

As discussed previously, an important part of MTMS involves the MAP. The MAP is a document that may empower the patient and promote self-care. The information on the MAP is important for both the patient and provider and facilitates communication among multiple providers. When a patient presents the PMR and MAP to all providers, complex medication information can be shared across the continuum of care. An example of M.C.'s MAP is included in Figure 1-3.

Because extensive information was communicated to the patient and other providers, follow-up (phone or face-to-face) would be appropriate and necessary to determine the resolution to the medication-related issues identified. Follow-up should occur in a timely manner, likely after M.C. has obtained the necessary laboratory test results and has been evaluated by her cardiologist as outlined in the plan. The follow-up should include questions related to the changes that were (or were not) made based on the practitioner recommendations and any new issues that have