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# Susan M. Ford, MN, RN, CNE Ret

for Nu for Nu unauthorized reproduction Professor Emeritus, Former Associate Dean for Nursing



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12th Edition

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9 8 7 6 5 4 3 2 1

Printed in China

Library of Congress Cataloging-in-Publication Data

ISBN-13: 978-1-975163-73-0

### Cataloging in Publication data available on request from publisher.

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My future—Pyrola Grothford, Rory Ford and Leighton Ford, my granddaughters; who I hope may see health care in their lifetimes become a right for all, not just a privilege for those who can pay.









In loving memory—Sylvia Jones, my mother and the nurse who suggest I follow her into the nursing profession as a career. We lost this wonderful woman in the year of COVID; not due to it, but because of it. Her own mother orphaned during the 1918 Influenza Pandemic, she started nursing school at the age of 17, during WWII. She was a delivery room nurse for some, school nurse to the neighborhood, and psych counselor to many friends and family. She was the strength we all hold in our hearts. Her dedication to thinking of others first and altruistic helping resulted in a number of health providers and educators in our family. Teaching us to think of others first, she spent her last day on earth personally hauling out the garbage canisters to the farm gate. Living to be 92 years old, I know she is proud of us, may we all carry on in her spunk and spirit!



### **Reviewers**

### Danette Ver Woert, MN, BSN, RN

Assistant Professor of Nursing Buntain College of Nursing, Northwest University condete and worker have inc. Unautoited reproduction of the content is provided to production of the content is provided to product on the content is product on the content is product on the content is provided to product on the content is provided to product on the content is product on the content is product on the content is provided to product on the content is product on the content i Kirkland, Washington



# Preface

*ntroductory Clinical Pharmacology* is one in a series of texts designed to assist beginning nursing students in acquiring a foundation of basic nursing theory and for developing clinical skills. Many publishers present a choice of texts offering information on drug action and activity. Yet, this text is uniquely written *by* nurses *for* nurses in an easy-to-read language, not only to teach the novice provider about the drugs but also to role model how to relay this information to clients.

Here are the key features new to the 12th edition across the entire text:

**Learning objectives** set the tone for students on what to find in a chapter. The language of learning objectives has been clarified and both learners and instructors know what level of understanding to expect from the information provided.

**NEW Tall man lettering** is now featured in Summary Drug Tables as well as Appendix B. Visual cueing to name differences helps bolster safety in drug administration.

**Two new alerts** are featured across chapters, LASA and PIP. Look-alike, Sound-alike (LASA) boxes list many of the drug names which, when spoken such as between providers, can be mistaken for other agents. Chapter displays alert providers to possible drug misinterpretation. Practice considerations (PIP) provide information about select drugs or actions that might not be critical, yet relevant to the drugs in the select chapters.

**Nursing assessment** is displayed as bulleted items. Providers need quick and organized presentation of information. By bullet listing key assessments, learners see the data needed for quick and succinct assessment. This helps learners to develop clinical reasoning skills by the delineation of crucial versus minor data.

Summary Drug Tables illustrate pronunciation of generic drug terms in an easier, learnable format.

**Pharmacology in Practice** discussion questions are threaded through every chapter to give the learner the opportunity to check knowledge and the instructor the means to stimulate discussion with learners.

### TEXT ORGANIZATION

The 12th edition of *introductory Clinical Pharmacology* is organized into 14 units. The unit expansion allows for more information on immunotherapy in general and cancer specifically. Changes and additions from the last edition are *italicized* below in addition to a brief explanation of unit information:

• Unit 1: Nursing Foundation of Clinical Pharmacology—is the basis of understanding drug therapy in order to better learn about pharmacology in general. Basic concepts include pharmacological concepts, techniques of administration and the math needed to provide safe dosing, how the nursing process and pharmacology work in tandem, and interacting with clients for best outcomes. New to 12th edition—greater emphasis on clarifying examples (e.g. FDA drug approval process), in-depth information on enteral and topical drug administration, the inclusion of TALLman lettering explanation (for later chapters), and viewing client problems in an expanded context of nursing.

• Unit 2: Drugs Used to Fight Infections—The infection chapter begins with bacterial microorganisms, moves on to viral, and the unit ends with fungi and protozoa. Antibacterial chapters (Chapters 6–9) group the drugs according to interaction with bacterial cells. This presentation helps in understanding how the different classes are similar and what to look for in terms of similar actions or adverse reactions. *Antibiotic stewardship is emphasized in these chapters*. Highlight of combination drugs used with diseases such as TB or HIV (Chapters 10 and 11) emphasizes methods to increase adherence to drug therapy and improving quality of life. Chapter 11 includes the expanding number of drugs to treat once acute illness (such as HIV and Hep C) shifting care to that of chronic conditions. Chapter 12 views drug therapy both in treating infections at home or those severe enough for hospitalization.

- Unit 3: Drugs Used to Manage Pain—Pain-assessment strategies, as well as the drugs for pain relief, are threaded through Chapters 13–15. A deeper look at chronic pain management includes a new pain relief ladder and information on the opiate crisis. Because of this, Chapter 15 now includes information on opiate antagonists, eliminating that chapter from this edition. As nurses, we need to acknowledge that many of our clients will have used marijuana for medical or recreational purposes. Therefore, it is important to provide knowledge of this drug and its uses as well as its effects and interactions. Inclusion of medical marijuana, written with neither the intent to support nor dismiss its use, is featured in Chapter 15. Many nurses never enter the operating room suites; therefore, Chapter 16 is now about anesthetic drugs with inclusion of conscious sedation.
- Unit 4: Drugs That Affect the Central Nervous System—When clients become stressed, mental health issues may surface. This can be a surprising experience for providers in nonpsychiatric settings such as acute med-surg floors or intensive care units. The chapters of this unit provide explanation and information to help reduce the stigma associated with clients labeled with a psychiatric diagnosis and see the benefit of drugs in helping care for those with mental health issues. The name change of Chapter 18 to Antidementia Drugs allows one to see it includes all drugs used beside the category of cholinesterase inhibitors, additionally, Alzheimer disease stages are explained according to the pathological stages of the disease to better correspond with different types of drugs used for different behaviors and pathology.
- Unit 5: Drugs That Affect the Peripheral Nervous System—Repetition and clarification of terminology in all chapters in this unit help students understand the importance of the neurologic system in many facets of drug therapy.
- Unit 6: Drugs That Affect the Neuromuscular System—Drug reclassification of *anticonvul*sant to *antiepileptic* terminology provides consistency in antiepileptic drug understanding and treatment.
- Unit 7: Drugs That Affect the Respiratory System—Over-the-counter products make selftreatment for respiratory conditions a growing concern. Both drugs and strategies for client teaching are updated in these chapters. Abuse of over-the-counter respiratory meds by adolescents is featured in this unit as well as new guidelines for Asthma Action Plans.
- Unit 8: Drugs That Affect the Cardiovascular System—National guideline updates are included in multiple chapters leading to the combination of cardiotonic and antiarrhythmic drugs into one chapter (Chapter 37). Encouraging students to use their skills at using clinical judgment with Pharmacology in Practice Case Studies in each chapter and linkages to the ancillary products will help the student to discover the polypharmacology issues when cardiac medications are prescribed in tandem with most any other category of drug.
- Unit 9: Drugs That Affect the Gastrointestinal System—Biologics used to treat inflammatory bowel diseases are now *connected to information in Unit 12*. These chapters focus on strategies for self-treatment of both upper and lower gastrointestinal issues.
- **Unit 10: Drugs That Affect the Endocrine System**—Antidiabetic medications in addition to insulin are provided in Chapter 40, which corresponds with the rise of clients being diagnosed with diabetes.
- Unit 11: Drugs That Affect the Urinary System—Clarity of information to help clients remain safe while using medications supporting healthy aging is highlighted in this unit.
- NEW Unit 12: Drugs That Affect the Immune System—Removing two earlier chapters allows for expansion into immunological agents. Vaccines are pulled out separately (Chapter 47) and new information is provided on immunostimulant and immunomodulating (or blocking) agents in Chapters 48 and 49. Information on biologic therapies for multiple chronic conditions as well as updated immunization schedules in easy-to-read versions makes information suitable to share with clients.
- NEW Unit 13: Drugs that Fight Cancer—With the addition of many biologic agents used in the treatment of cancers, another chapter exclusive to these agents was added to the text.

Chapter 50 includes drug categories known as the traditional chemotherapy agents, and Chapter 51 includes immunotherapy and target agents used in the treatment of cancers.

• Unit 14: Drugs That Affect Other Body Systems—Topicals are featured in Chapter 52, drugs for ear and eye disorders in Chapter 53, and Chapter 54 includes elements and parenteral therapy.

### **FEATURES**

Written with client outcomes in mind, complex concepts are introduced in simplified language, helping learners to grasp concepts quicker and to use client teaching information right from the text leading to better understanding on the part of the client and adherence to treatment strategies.

### **Benefit to the Instructor**

The basic explanations presented in the text are *not* intended to suggest that pharmacology is an easy subject. As we know it, drug therapy is one of the most important and complicated treatment modalities in modern health care. This text is written to help you *teach* the latest pharmacologic information available by including:

- Clear, concise language to introduce learners to the basics of pharmacology.
- Presentation of drugs in a way to make integration of this text into concept-based curricula seamless and effortless.
- Learning objectives are leveled to make your expectations of knowledge retention clear to the learner.
- Comprehensive bibliography entries that link the text to the latest evidence-based information and practice.

The new, or improved, features that make this the best pharmacology text for teaching your students include the following:

- Nursing process planning language makes client problem recognition understandable to an array of health care disciplines as well as nursing.
- Special features such as *Alerts* and *Considerations*, which include information to care for a more diverse client population.
- Removal of old drug brand names that have lost their exclusive patents and confuse learners when used.
- New to this edition are highlighted questions embedded in the text, to make the learner stop, ponder, and examine learning retention. All skills need to develop clinical judgment in the field.

### Benefit to the Learner

As a novice provider, this text gives you the introduction and foundation you need to begin developing your own clinical judgment skills. This text is written to help you *learn* the latest pharmacologic information available by including:

- Drug therapy explained uniquely from a nursing perspective.
- Connection of drug therapy to the basic nursing theory you are learning in your nursing curriculum.
- Presentation in an easy-to-read and follow format that helps you understand the drugs and their effects on the human body, which in turn motivates you to continue to learn more about this sub-
- ject independently and helps you to provide better care, educate clients, and improve outcomes.
- A nursing process section in each chapter that uses a familiar step-by-step method to show how
  medications are used in the care of clients. Elements of the nursing process—assessment, analysis,
  planning, intervention, and evaluation—illustrate basic and practical nursing skills to help develop
  clinical reasoning in order for you to help clients meet their health care needs, and to improve
  adherence to treatment, all designed for better client outcomes.
- Medication calculation using principles of safe practice rather than mathematical formulas used in traditional math classes. Learning focuses on reducing medication errors that result from mathematical mistakes rather than on the traditional arithmetic exercises.
- Seven clients introduced in Chapter 5, whose health issues are woven into subsequent chapters in order to build a story of how drugs impact real people. Your ability to use outcome strategies and communicate what you do to support client and family confidence in learning self-management

skills of medication administration is highlighted using health literacy principles and appreciation of cultural diversity using one of these seven clients individually featured in each chapter.

- Specific quiz review items that are directly linked to the latest NCLEX test plan.
- A list of abbreviations on the inside back cover for easy reference.
- Informational data to construct mind mapping visuals of the case study clients when used in conjunction with the suite of product ancillaries or for those who prefer—the *Study Guide to Accompany Introductory Clinical Pharmacology*, 12th Edition, with either product, it provides you with multiple opportunities to identify potential drug–drug interactions, once again helping you as you build your skills of reasoning and clinical judgement.

### **Building Clinical Judgment**

Pharmacology courses are typically taught preprogram or as a preclinical course in nursing programs. Therefore, the focus of concepts in this text are to prepare the learner with a good foundation of lower layers of clinical judgment skill building for when learners begin clinical and lab courses where they are able to connect the foundations of pharmacology with clinical situations.

This title provides repetition of concepts, introduction to case studies, and mind mapping tools for learning to help provide a base for clinical judgment development, and subsequent nursing competency.

Specifics found in this text to develop clinical judgment include the following:

- Chapter 4 discusses Nursing Process within the context of medication administration. Each subsequent drug chapter has a *Nursing Process—Steps to Build Clinical Judgment* section to help learners understand how select drug categories impact clients.
- Chapter 5 introduces learner to seven clients, who are randomly featured in case study situations in each subsequent drug chapter helping learners examine medications in a client context.
- LASA (look alike, sound alike) and Nursing Alerts in addition to health-related considerations are highlighted in each chapter to help learners recognize and attend to cues which may vary from routine.
- Case studies with visual mind mapping exercises are offered in the ancillary package. Learners can layer and build scenarios in order to understand how and begin to anticipate how drugs interact with each other and the disease processes involved resulting in positive outcomes, bothersome side effects, or serious adverse reactions.

### What My Nursing Experiences Offer in This Text

To learn skills one needs repetitive practice, and nurses gain this in the clinical setting. This means as elders we must step aside so that new nurses may gain that experience. Retiring from paid clinical positions does not mean we stop learning; I continued to gain teaching experience as a volunteer scripted/standardize@client in the Nursing Simulation Center at Swedish RN Residency Program and learn about client experiences as a volunteer facilitator in chronic illness workshops at Kaiser Foundation Health Plan of Washington. COVID changed all that, being isolated at home and privileged to have good resources I had the time to study, research drug interactions, and speak to nurses regarding the clinical decision making happening for both critical and what we now think of as routine care. I listen to what new nurses and clients need in our ever-changing health care systems. Participating as a healthcare volunteer in COVID-19 vaccination clinics; I witnessed the exhaustion of providers, and both the fear and jubilation of those getting the vaccine. These experiences help me to appreciate what novice nurses need in their pharmacologic education and how clients understand what we say as we communicate about drugs in our interventions and teaching. Where we have to be expedient, yet demonstrate a high degree of caring in our interactions with every client. This text is a blending of this newly gained insight with well over 40 years of nursing practice and teaching experience in mental health, acute care, operating room, ambulatory care, home health, and hospice settings, as well as holding nursing certification in areas such as oncology, medical-surgical clinical nurse specialist, and as a certified nurse educator.

### As You Learn and Enter Practice

You may find that certain drugs or drug dosages described in this publication may no longer be available. Likewise, there may be new drugs on the market that were not approved by the U.S. Food

and Drug Administration (FDA) at the time of publication. With the availability of computers, smart phones, and other Internet resources, current information is always there for verification of any drug question and should be checked when you do have a question before administering a drug. Do not forget that your colleagues, clinical pharmacists, and primary health care providers are also resources for information concerning a specific drug including dosage, adverse reactions, contraindications, precautions, interactions, or administration. Check out my pharmacology blog - things I can't get to press in this book, you will see there - https://icp-ford.blogspot.com/

### **TEACHING AND LEARNING RESOURCES**

To facilitate mastery of this text's content, a comprehensive teaching and learning package has been developed to assist faculty and students.

### **Resources for Instructors**

Tools to assist you with teaching your course are available upon adoption of this text at http:// thepoint.lww.com/Ford12e

- A **Test Generator** lets you put together exclusive new tests from a bank containing hundreds of questions to help you in assessing your students' understanding of the material. Test questions link to chapter learning objectives.
- **PowerPoint Presentations** have been totally revised to provide greater flexibility to the instructor for use in-class, as online study, or for a completely self-paced course. These provided an easy way for you to integrate the textbook with your students' classroom experience, either via slide shows or handouts. Multiple-choice and true/false questions are integrated into the presentations to promote class participation and allow you to use iClicker technology.
- An **Image Bank** lets you use the photographs and illustrations from this textbook in your PowerPoint slides or as you see fit in your course.
- **Case Studies** with related questions (and suggested answers) give students an opportunity to apply their knowledge to a client case similar to one they might encounter in practice.
- **Pre-Lecture Quizzes** (and answers) are quick, knowledge-based assessments that allow you to check students' reading and are written in the Next-Generation NCLEX style offering additional practice in this new format.
- Guided Lecture Notes walk you through the chapters to help you present information in an informative and educational manner.
- **Discussion Topics** (and suggested answers) are based off of the Pharmacology in Practice questions of the text. Helping students connect information from the book with situations in the clinical setting, they can be used as conversation starters or in online discussion boards.
- Plus Syllabi (including an online self-paced course), Lesson Plans, QSEN Competency Maps, and Assignments for discussion or mind mapping exercises).

### **Resources for Students**

An exciting set of free resources is available to help students review material and become even more familiar with vital concepts. Students can access all these resources at http://thePoint.lww.com/ Ford12e using the codes printed in the front of their textbooks.

**NCLEX-Style Review Questions** for each chapter help students review important concepts and practice for the NCLEX.

- Concepts in Action Animations bring pharmacology concepts to life.
- Watch & Learn Videos explain how to prepare unit dose-packaged medications as well as administering oral medication, subcutaneous injections, and intramuscular injections. (Icons in the textbook direct readers to relevant videos.)
- Journal Articles provided for each chapter offer access to current research available in Wolters Kluwer journals.
- Plus Learning Objectives, Drug Monographs, Dosage Calculation Quizzes, and an Audio Glossary.

### **Study Guide**

The *Study Guide to Accompany Introductory Pharmacology*, 12th Edition, offers exercises, puzzles, and multiple-choice questions to quiz your pharmacologic knowledge. In the 12th edition, the same seven clients as the text are included to continue the real-life case studies connected to situations in the text. Mind mapping templates are provided to help you learn visually as you go. These maps, which correlate to each of the text case study clients, give you a visual method to see drug–drug interactions, and anticipate problems of polypharmacy as you follow the stories of these seven clients in the text and study guide.

### A FULLY INTEGRATED COURSE EXPERIENCE

We are pleased to offer an expanded suite of digital solutions and ancillaries to support instructors and students using *Introductory Clinical Pharmacology*, 12th Edition. To learn more about any solution, please contact your local Wolters Kluwer representative.

### Lippincott CoursePoint+

*Lippincott*<sup>®</sup> *CoursePoint* is an integrated, digital curriculum solution for nursing education that provides a completely interactive experience geared to help students understand, retain, and apply their course knowledge and be prepared for practice. The time-tested, easy-to-use, and trusted solution includes engaging learning tools, evidence-based practice, case studies, and in-depth reporting to meet students where they are in their learning, combined with the most trusted nursing education content on the market to help prepare students for practice. This easy-to-use digital learning solution of *Lippincott*<sup>®</sup> *CoursePoint*+, combined with unmatched support, gives instructors and students everything they need for course and curriculum success!

### *Lippincott*<sup>®</sup> *CoursePoint*+ includes:

- Leading content provides a variety of learning tools to engage students of all learning styles.
- A personalized learning approach gives students the content and tools they need at the moment they need it, giving them data for more focused remediation and helping to boost their confidence and competence.
- Powerful tools, including varying levels of case studies, interactive learning activities, and adaptive learning powered by PrepU, help students learn the critical thinking and clinical judgment skills to help them become practice-ready nurses.
- Preparation for Practice improves student competence, confidence, and success in transitioning to practice.
  - *vSim*<sup>®</sup> for Nursing: Codeveloped by Laerdal Medical and Wolters Kluwer, *vSim*<sup>®</sup> for Nursing simulates real nursing scenarios and allows students to interact with virtual patients in a safe, online environment.
  - Lippincott<sup>®</sup> Advisor for Education: With over 8500 entries covering the latest evidence-based content and drug information, Lippincott<sup>®</sup> Advisor for Education provides students with the most up-to-date information possible, while giving them valuable experience with the same point-of-care content they will encounter in practice.
- Unparalleled reporting provides in-depth dashboards with several data points to track student progress and help identify strengths and weaknesses.
- <sup>1</sup> Unmatched support includes training coaches, product trainers, and nursing education consultants to help educators and students implement *CoursePoint* with ease.



# Acknowledgments

### **MY SINCERE APPRECIATION**

Few people besides textbook writers really know how these books are made. They start on a computer in a home or office, materials take flight electronically to travel cross country, and return to the writers. Documents are sent to places around the world I have never traveled and are edited and processed by people I will never physically meet. Then the finished book makes it to you, the reader. You may find some mistakes - and with all the hands these pages have passed through, I'm not surprised. But, drop me an email and let me know so we can correct them - ford10ip@gmail.com. I might send you a nice Thank-you! I would like to extend a special thanks to the employees of TNQ Technologies - thank you for your dedication during cyclones that hit India, destruction of homes, caring for you loved ones with COVID, having to find electricity to power your computers and so much more to produce this book - from the other side of the world. It does take a global village - to make the world function properly - Thank-you!

To my literary team at Wolters Kluwer—writing a text during a pandemic might sound easy; sit at home by yourself and type away. Living that experience—proves different. The motivation to do the conceptualizing, research, and editing does not just happen. That creativity is grown out of interactions, and when those routine interactions cease—two specific people stepped up their game.

Thank you—Julie Vitale and Jonathan Joyce—my editorial team. You two got me through unanticipated divots in the publishing process, COVID isolation, family illness, deaths, and births keeping me on track. You connected with me when I needed it most. Think of me when you hear the following words...

To Julie—Iditarod, Taylor's ham, the Farm, Formula 1, and Rory's antics.

To Jonathan—No summer camp, da Bears, Go Hawks, who gets Wilson, let's talk about baseball instead.

To the many others involved at WK, it is impossible to single out the importance of one person over another—thank you for making every edition better than the one before.

To my extended family, friends, colleagues, and students-turned fellow nurses: thank you for being there with ideas and stories to share.

To my sister. Nancy Rauch, iBest college faculty member, thank you for helping make math skills real to these students. To Madison Hjelmeland, LPN and Finnly Jones, LPN (my nieces) thanks for keeping me connected to the student experience and continuing the tradition of nursing in the family. To Dr. Tiffany Zyniewicz of Northwest University, stepping in to help develop a contemporary and useful ancillary package for nurse educators. To my friends, Pam and Marion, thank you for keeping connected and willing to listen—keeping me motivated to the end of this project.

Most importantly, to my family—Jerry, Stephanie, Eric, Peter, Lexy, and those darling granddaughters—who inspire me on a daily basis to be the best person and nurse possible!

-S. F. (87ord)



# User's Guide

### UNIT STRUCTURE AND ORGANIZATION

Learners are more successful when they know *how* to use the text as well as what is in the text. Here are some quick tips on how to use your text more effectively. Fourteen units offer 54 chapters providing information in learnable segments that are not overwhelming to the learner. Organization of the text in this manner allows you to move about the chapters easily when these specific areas of content are covered in your program curriculum.

The text starts with the basic fundamentals of drug therapy. Then units about infection and pain, followed by units about drugs related to different body systems. These units are written in a head-to-toe sequence, making the specific drugs easier to find.

Learning about drug therapy is easier when you can connect the information with life-like clinical experiences. In Chapter 5, you will be introduced to a group of clients in the clinic setting. Their stories establish for you a context in which to begin learning about the selected drugs and their real-world application.





# BEGINNING OF THE CHAPTER

The chapter opening page is designed to guide you, the learner, in organizing your study routine as you learn the essential elements of drug therapy in each chapter.

### **Learning Objectives**

These define what you will learn in a specific chapter. Review the objectives first to help you understand what you need to learn after reading the chapter.

### **Key Terms**

With accompanying definitions, the Key Terms help you build your vocabulary. Look for **bold type** in the text at first mention of the word in the chapter to remind you of the definition.

### **Drug Classes**

This gives you a sense of how drugs are grouped according to similar properties. Learning these groupings helps you identify potential errors and safety concerns.

### **Pharmacology in Practice**

Each chapter features a case study individual dealing with an issue related to drugs featured in the chapter. Scenarios focus on assessment, administration, or teaching issues that have an impact on reallife patients. Their stories help you to focus your attention on the concepts important to patient care.

### **DRUG INFORMATION**

### **Consistent Framework**

Each chapter presents the drugs in such a way that you learn to recognize and respond to client questions quickly and accurately. Illustrated concepts guide you as each chapter features information about the drug class in a logical and sequential order as **Action, Uses, and Adverse Reactions**—the concepts you, the nurse, deal with on a consistent basis. This is followed by **Contraindications, Precautions, LASA alerts, and Interactions**—all items typically reviewed earlier and considered by other health care providers, yet at the same time important for you to know to provide safe drug administration to your clients.

### **Special Features**

Special features are sprinkled throughout the text to direct you to priority information about the drugs or individuals who will receive the drugs.

### Nursing Alerts

Quickly identify urgent nursing actions in the management of the patient receiving a specific drug or drug category.

### Lifespan Considerations

Draw your attention to specific populations at risk or needing specific administration considerations (e.g., gerontology and pediatric). Because texts are written dealing specifically with obstetrical and pediatric patients, the primary focus of these alerts is for geriatric patients, or when specific populations (e.g., women of childbearing age or transgender persons) take a medication that will interact differently than the general population.

### **Drug Interaction Tables**

A quick visual scan of these tables can tell you if a patient is likely to have a problem when multiple drugs are given. Using these tables as you construct concept maps on the case study patients in each chapter will help you identify harmful interactions, before you see them happen in practice.

### **Herbal Considerations**

Provide information on herbs and complementary and alternative remedies used by patients under your care. Additional information is provided in Appendix D where examples of a number of natural products are provided.

### **Practice Considerations**

Provide information about select drugs or actions that might not be critical, yet relevant to the drugs in the select chapters.

NURSING ALERT Clients receiving antiretroviral drugs for HIV infection may continue to contract opportunistic infections and other complications of HIV disease. Monitor all clients closely for signs of infection such as fever (even low-grade fever), malaise, sore throat, or lethargy. All caregivers are reminded to use good hand hygiene technique.

### Lifespan Considerations

### **Pediatrics**

Severely ill children infected with it fluenza show significant improvement and decreased mortality when treated within 48 hr of flu symptom recognition with NAI drugs.

Interacting Drug	Convoon Use	Effect of Interaction
probenecid	Gout treatment	Increased serum levels of the antivirals
cimetidine	Gastric upset, heartburn	Increased serum level of the antiviral valacyclovir

### Herbal Considerations

Individuals use St. John's wort (Fig. 11.3) for antibacterial, antidepressive, and antiviral effects of the supplement. This herbal supplement is one of the most commonly purchased herbal products in the United

### PRACTICE CONSIDERATIONS

Owing to the high rates of viral resistance the drugs rimantadine and amantadine are no longer recommended for treatment of influenza type A.

### NURSING PROCESS AND DRUG THERAPY

Uniquely presented, nursing actions regarding drug information are provided in the context of a nurse's clinical practice. The nursing process is featured as a practical guide to building clinical judgment in the context of drug therapy provided to clients.

Assessment	Here are the questions to ask for the information needed both before and during drug therapy.		
Analysis and Planning	Frequently seen Nursing Problems are listed and suggested outcomes for patient responses to specific drugs or drug therapy.		
Implementation	Promoting an Optimal Response Gives you specific information to use for effective and safe administration.		
	Monitoring and Managing Patient Needs Gives you a number of strategies to use in your practice as a nurse to help patients deal with the drugs they are taking.		
	Educating the Patient and Family LPN/LVNs are the first and often primary contacts in community settings (e.g., assisted living, long-term care, clinics, and offices). You will be the one to teach and provide information to patients and families about the drugs. Here are practical tools and methods to help you work with people to be sure they are taking medications correctly and watching for signs and symptoms.		
Evaluation	Bulleted lists highlight important measures and help you decide whether the strategies you use provide the best outcomes while building confidence in your patient's abilities to adhere to medication plans.		

### END OF THE CHAPTER

Here is where you determine what you have learned from reading each chapter. Information is summarized in an easyto-read format, giving you the opportunity to demonstrate your growing clinical reasoning skills by applying information in the chapter case study. Once you review the chapter, use the review questions to demonstrate your skill as you would when you take the NCLEX examination.

### **Pharmacology In Practice: Clinical Reasoning**

Each chapter ends with a return to the case study patient. Realistic patient care situations help learners apply the material contained in the chapter by exploring options and making clinical judgments related to the administration of drugs. The case histories of seven patients are used, and different aspects of care are presented in different chapters like puzzle pieces, making connections for learners to appreciate the complex issues in providing care to both individuals and families. Coupled with information from the Study Guide to Accompany Roach's Introductory Clinical Pharmacology the learner is encouraged to map out patient problems discovering potential complications or areas for improved patient care.

### **Key Points**

Key points are summarized and the important concepts of the chapter are listed to help you determine if you have mastered the learning objectives.

### **Summary Drug Tables**

Conveniently placed, these tables provide a list of drugs from the classes discussed in each chapter. Current names (generic and, when appropriate, brand names), uses, frequent adverse reactions, and general dosing information are given in an accessible, easy-to-read format.

### CHAPTER REVIEW

Clien trade nize name <u>Gene</u> 2. da 3. os 4. va

w Your Drugs ts sometimes know ) name and not the both names, match of the same medic	w a medication by the brand (or generic name. To help you recog- a the brand name with the generic ation.	4.
rric Name	Brand Name	
yelovir runavir eltamivir lacyelovir	A. Prezista B. Tamiflu C. Valtrex D. Zovirax	5.

wir 200 mg. The de

### Calc

The client is prescribed acyclovir 20 is available in 100-mg tablets. The m The nurse is to administer 100 mg of zidovudin The drug is available as syrup 50 mg/5 mL. The

### Prepare for the NCLEX

curs by invading a vely by blood-born

ration of antiretrovirals can result in

body fat redist on of the skir

- bonnet Guest fores is prescribed one inhalation of zanamivin hr. The drug is available as one 5-mg bl ation and is to be given with a Diskhales low many milligrams will the nurse er in a 24-hr period?



### **Know Your Drugs**

Use the matching exercise to identify drug names and connect generic with brand names to help you recognize the potential for and prevention against using the wrong drug.

### **Calculate Medication Dosages**

Practice the math skills to learn accurate drug dosing and recognize the potential for error, thus ensuring that you give the correct dose.

### **Prepare for the NCLEX**

At the end of each chapter, you'll find questions to test your knowledge base and retention of pharmacology information. Here questions allow you to tes your knowledge of the material.

- 1. Recall the facts provides questions about information and content retention.
- 2. Analyze the facts provides analysis and application questions.
- 3. Alternate-Format Questions provide you experience in applying what you've learned in a different manner.

Special Features Questions are structured like the NCLEX examination. The design helps you become familiar with the language and format of NCLEX testing.

Numbered (1, 2, 3, 4) Distractors The NCLEX provides a single question on a computer screen. The options you are given are listed as numbers. Distractor options in these questions are labeled 1, 2, 3, 4 instead of A, B, C, D-again, to simulate the NCLEX examination.





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# **UNIT 1** Nursing Foundation of Clinical Pharmacology

B ecoming a nurse means medication administration and management are possibly the most significant tasks of your nursing practice. In an institutional setting, the clients rely on nurses to accurately administer and monitor medications to keep them safe and promote health. Although clients at home and in the clinic setting are more independent, they rely heavily on the knowledge and instruction given by nurses to learn how to become good managers of their own health care needs (Bonsall, 2016). Both situations require a competent nursing professional who has a strong foundation of clinical pharmacology.

Unit 1 provides you with the foundation for understanding pharmacology in the context of nursing clinical practice. Three of the five chapters in this unit specifically discuss concepts focal to nursing: drug administration, nursing process, and client teaching. In addition, the general principles of pharmacology and the mathematics involved in dosage calculation are concepts used by all providers. These concepts are included in their own chapters. The following is a brief summary of the content in each chapter of Unit 1.

Basic principles are covered in Chapter 1, beginning with how drugs are derived from natural sources, such as plants, or made synthetically. Other key concepts include facts about drug categories and the differences between a prescription drug (those given under the supervision of a licensed health care provider) and a conprescription drug (those obtained over the counter and designated as safe when taken as directed). Finally, you will gain an understanding of how drugs undergo a series of steps to be processed, utilized, and eliminated by the body—this is the basis for the study of pharmacology for health care providers.

Administration of a drug is primarily the responsibility of the nurse and is discussed in Chapter 2. Nurses have the duty to safely provide client care by correctly administering the medication prescribed by the primary health care provider. This is achieved by learning and following the principles of drug administration, proper technique, and using medication systems correctly.

Chapter 3 provides both the opportunity to practice drug dosage calculations and an overview of the tasks that you will undertake to be sure drug doses are correct *before* administration. Your ability to correctly calculate mathematical problems is one of the most important steps in providing safe care to clients. Mastering steps in drug administration and delivery help to ensure accuracy in those math calculations.

Nursing process concepts are covered in Chapter 4. Most clients experience problems of anxiety or a lack of knowledge regarding new medication routines. The nursing process is used by the nurse to develop an individualized care and teaching plan for use when medications are ordered. This process is used to help members of the health care team provide effective and efficient client care.

To complete the first unit components needed for successful client teaching are described in Chapter 5. It is crucial that the client understands basic information about the medication prescribed, including the dosage, how to take the medication, the expected effect, and adverse reactions. In the textbook many examples are given using the case study method. In this chapter, the group of individuals receiving nursing care in an ambulatory setting are introduced. Their stories are designed to help you understand how all this information is used in the nursing care of clients receiving drug therapy. You will learn how concepts are put into practice using these case study individuals throughout the textbook.

By understanding the basic principles of pharmacology, you can build a sound knowledge base of the drugs used to help clients maintain their highest levels of wellness.



### Key Terms

**absorption** a drug is moved from the site of administration to body fluids; first process during pharmacokinetics

adverse reaction undesirable drug effect

**allergic reaction** hypersensitive reaction by the immune system; it presents as itching, hives, swelling, and difficulty breathing

**anaphylactic shock** sudden, severe hypersensitivity reaction with symptoms that progress rapidly and may result in death if not treated; also called *anaphylactic reaction* or *anaphylactoid reaction* 

**angioedema** localized wheals or swellings in subcutaneous tissues or mucous membranes, which may be caused by an allergic response; also called *angioneurotic edema* 

**bioavailability** the proportion of a drug available to body tissues when it reaches the circulatory system

**controlled substances** drugs that have the potential for abuse and dependency, both physical and psychological

**cumulative drug effect** when the body is unable to metabolize and excrete one dose of a drug before the next is given

**complementary/alternative medicine** (CAM) group of diverse medical practices or products not presently part of conventional medicine

**distribution** drug moves from circulation to body tissue or a target site

**drug idiosyncrasy** any unusual or abnormal response that differs from the response normally expected to a specific drug and dosage

**drug tolerance** decreased response to a drug, requiring an increase in dosage to achieve the desired effect

(continued)

# General Principles of Pharmacology

### Learning Objectives

On completion of this chapter, the student will:

- 1. Define the term *pharmacology*.
- 2. Compare and contrast the different names assigned to drugs.
- 3. Distinguish between prescription drugs, nonprescription drugs, and controlled substances.
- 4. Discuss drug development in the United States.
- 5. Compare and contrast the various types of drug activity and reactions produced in the body.
- 6. Identify factors that influence drug action.
- 7. Explain drug tolerance, cumulative drug effect, and drug idiosyncrasy.
- 8. Discuss the types of drug interactions that may be seen with drug administration.
- 9. Examine the nursing implications associated with drug actions, interactions, and effects.
- 10. Discuss the use of herbal medicines.

Pharmacology is the study of drugs and their action on living organisms. For nurses, a sound knowledge of basic pharmacologic principles is essential in administering medications safely and monitoring clients who receive these medications. This chapter presents a basic overview of the pharmacologic principles needed to understand medication administration. Finally, **herbal medicines** as they relate to pharmacology are discussed.

Over the last century, drugs have changed the way health care providers treat clients. In the early 1900s, individuals died from infections and surgical complications partly because of a lack of sanitary conditions and the fact that medicines used to combat infection did not exist at the time. One example is the discovery of drug substances (antibiotics), which changed an infection that meant certain death to now a diagnosis of a treatable acute and typically short-lived health condition. Drug therapy also means that clients lacking certain substances in their bodies, such as insulin, or those diagnosed with cancerous tumors can now live long and productive lives.

Medications are substances derived from natural sources, such as plants and minerals, or they are synthetically produced in a laboratory. An example of a drug derived from a natural source is digitalis, which is an extract from the foxglove plant that acts as a potent heart medication. Mipomersen (brand name Kynamro) is a chemically engineered drug designed to target specific cell components in people with high cholesterol.

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### Key Terms (continued)

**excretion** elimination of a drug from the body

**first-pass effect** action by which an oral drug is absorbed and carried directly to the liver, where it is inactivated by enzymes before it enters the general bloodstream

**half-life** time required for the body to eliminate 50% of a drug

**herbal medicine** type of complementary/alternative therapy that uses plants or herbs to treat various disorders; also called *herbalism* 

**hypersensitive** undesirable reaction produced by a normal immune system

**metabolism** drug is changed to a form that can be excreted

**metabolite** inactive form of the original drug

**nonprescription drugs** drugs designated by the US Food and Drug Administration (FDA) to be safe (if taken as directed) and obtainable without a prescription; also called *over-the-counter* (OTC) drugs

**pharmaceutic** pertaining to the phase during which a drug dissolves in the body

**pharmacodynamics** study of the drug mechanisms that produce biochemical or physiologic changes in the body

**pharmacokinetics** study of drug transit (or activity) after administration

**physical dependency** habitual use of a drug, where negative physical withdrawal symptoms result from abrupt discontinuation

**prescription drugs** drugs the federal government has designated

as potentially harmful unless their use is supervised by a licensed health care provider, such as a nurse practitioner, physician, or dentist

### psychological

**dependency** compulsion or craving to use a substance to obtain a pleasurable experience

**receptor** *in pharmacology,* a reactive site on the surface of a cell; when a drug binds to and interacts with the receptor, a pharmacologic response occurs

### risk evaluation and mitigation

**strategies (REMS)** program of the FDA, designed to monitor drugs that have a high risk compared with benefit ratio

**teratogen** drug or substance that causes abnormal development of the fetus, leading to deformities

toxic poisonous or harmful

### **DRUG NAMES**

To begin understanding the principles of pharmacology, let us start with learning about how drugs are named. Once you understand this concept, it will be easier to understand classes and categories of drugs, as well as federal regulations pertaining to drugs and how they are developed. Throughout the process of development, drugs may have several names assigned to them. These different names can be confusing. Therefore, if you have a clear understanding of the different names used, you can promote client safety by reducing errors.

A drug may have three different names:

• Chemical name—a scientific term that describes the molecular structure of a drug; it typically is the chemical component of the drug.

• Generic name—considered the official name of a drug and is the name given to a drug that can be made or marketed by any company; it is nonproprietary, meaning it is not owned by any specific agency.

ð

• Trade name—selected by a specific company producing the drug for marketing purposes. When a drug name is followed by a trademark symbol <sup>TM</sup> or a registered trademark symbol ®, this signifies that it is the trade or brand name.

Table 1.1 identifies the various chemical, generic, and trade names and provides an example and explanation for each name.

The generic name is the official name that is given to a drug by the US Food and Drug Administration (FDA). It also is the name found in the *National Formulary* or the *US Pharmacopeia* for an approved drug. To avoid confusion, it is best to use the generic name. One safety practice is the

DRUG NAME	EXAMPLE	EXPLANATION
Chemical name (scientific name)	Example: ethyl 4-(8-chloro-5,6-dihydro-11 <i>H</i> - benzo[5,6] cyclohepta[1,2- <i>b</i> ]-pyridin-11- ylidene)-1-piperidinecarboxylate	Gives the exact chemical structure of the drug and placing of the atoms or molecules; the chemical name is not capitalized
Generic name official or nonproprietary name)	Example: loratadine	Name given to a drug before it becomes official; may be used in any country, by all manufacturers; the generic name is typically not capitalized
Trade name (brand name)	Example: Claritin®	Name that is registered by the manufacturer and is followed by the trademark symbol; the name can be used only by the manufacturer; a drug may have several trade names, depending on the number of manufacturers; the first letter of the trade name is capitalized

### TABLE 1.1 Drug Names

use of Tall man lettering for drugs that look or sound alike. Using capital letters within the name of a drug helps health care providers to distinguish different drugs that have similar or confusing names. You will find examples in the chapter Drug Summary Tables, LASA alerts, and in Appendix B.

### DRUG CLASSES AND CATEGORIES

Different organizations classify drugs for different reasons. Medicare and Insurance companies classify drugs in a tier system for cost and coverage purposes. The Drug Enforcement Agency (DEA) defines drugs according to legality. In our study of pharmacology, we are going to look at how drugs are developed by pharmaceutical companies, named, and then classified.

Drugs are organized into different classes and categories to help people better understand how they work in the body. A drug may be classified by the chemical type of the active ingredient or by the way it is used to treat a particular condition. Each drug can be classified into one or more drug classes. For instance, in Unit 2, drugs that retard or destroy pathogens are classified as anti-infectives. In each chapter, these drugs are further categorized by the way they work (such as antivirals) or their chemical structure (e.g., penicillins). In addition, once a drug is approved for use, the FDA assigns it to one of the following categories: prescription, nonprescription, or controlled substance. This method of assignment helps you to understand the ease of accessibility of a drug to the client. To help you learn these classes, a list is included at the start of each chapter.

### **NURSING ALERT**

Study the patterns used in the naming of drugs. This may help you to identify names and prevent medication errors. Certain portions of the drug name may be similar in specific drug classes or categories. For example, beta-adrenergic (β-adrenergic) blocking drug names end with "Iol." *Atenolol, metoprolol,* and *propranolol* are all antihypertensive drugs from the same category.



### PHARMACOLOGY NO PRACTICE

DRUG RECOGNITION

Mr. Garcia is prescribed the drug metoprolol. Use your drug resources to identify the three names for this drug and the drug's category and class.

### **Prescription Drugs**

Prescription drugs, also called *legend drugs*, are the largest category of drugs. **Prescription drugs** are prescribed by a licensed health care provider. The prescription (Fig. 1.1) contains the name of the drug, the dosage, the method and times of administration, and the electronic signature of the licensed health care provider prescribing the drug. Typically, the health care provider writes the prescription electronically and it is transmitted to the pharmacy. A paper copy

XYZ PHARMACY SYSTEM Electronically Transmitted to Smith Pharmacy 1234 Broad Street Anytown, State, Zip				
Date: 10/20/2 Rx # 987654	Date: 10/20/20yy Rx # 9876543 ID # 11223344			
Last Name: First Name: DOB: Sex: Address:	Patient Information Jones Mary 10/18/YY F 567 King Street Anytown, State, Zip			
Phone:	(XXX)-888-7777			
Drug Name: Strength: Quantity: SIG: Refills: Label:	Drug, SIG, and Refill Information Gabapentin 100 mg 60 Dose Form: capsules Take 1 capsule at bedtime 6 yes			
Prescriber Information Last Name: Brown First Name: James M Address: 100 Main Street Anytown, State, Zip				
DEA: NPI:	CB1234XXX 9876543XXX			

FIGURE 1.1 Example of an electronically transmitted prescription form.

may be printed for a client if a pharmacy outside the health care system will be used to obtain the medication.

Drugs requiring prescription are designated as such by the federal government because they are potentially harmful unless their use is supervised by a licensed health care provider, such as a nurse practitioner, physician, or dentist. Supervision is important because, although these drugs have been tested for safety and therapeutic effect, prescription drugs may cause different reactions in some individuals.

In institutional settings, the nurse administers the drug and monitors the client for therapeutic effect and **adverse reactions** (undesirable effect). Some drugs have the potential to be **toxic** (harmful). As a nurse, you will play a critical role in evaluating the client for toxic effects. When these drugs are prescribed to be taken at home, you will provide client and family education about the drug.

### Nonprescription Drugs

**Nonprescription drug** designation is made by the FDA when the drug is safe (taken as directed) and obtainable without a prescription. These drugs are frequently called over-the-counter (OTC) drugs and may be purchased without a prescription in a variety of settings, such as a drug-store, local supermarket, or a large warehouse retailer (e.g., Costco or Sam's Club). OTC drugs include those given for symptoms of the common cold, minor aches and pains, constipation, diarrhea, heartburn, and minor fungal infections.

Labeling requirements give the consumer important information regarding the drug, dosage, contraindications, precautions, and adverse reactions. Consumers are urged to read the directions carefully before taking OTC drugs. Yet, these drugs are not without risk. For example, acetaminophen, commonly used for pain relief, is also found in many OTC products, such as cough and cold remedies. When taken for both pain and in a cold remedy, this accumulative amount of the drug can potentially harm a person's liver.

### **Controlled Substances**

**Controlled substances** are the most carefully monitored class of drugs. These drugs have a high potential for abuse and may cause physical or psychological dependency. **Physical dependency** is defined as the habitual use of a drug in which negative physical withdrawal symptoms result from abrupt discontinuation; it is the body's dependence on repeated administration of a drug. **Psychological dependency** is a compulsion or craving to use a substance to obtain a pleasurable experience. It is the mind's desire for the repeated administration of a drug. Physical and psychological dependence do not always occur together, yet one type of dependency may lead to the other.

The Controlled Substances Act of 1970 established a classification system for drugs with abuse potential. The act regulates the manufacture, distribution, and dispensing of these drugs. The Controlled Substances Act divides drugs into five groups, called schedules, which are based on the substance's potential for abuse and physical and psychological dependence. Appendix A describes the five schedules. Prescription practices of the primary health care provider for controlled substances are monitored by the DEA. Under federal law, limited quantities of certain schedule V drugs may be purchased without a prescription, with the purchase recorded by the dispensing pharmacist. In some cases, state laws are more restrictive than federal laws and impose additional requirements for the sale and distribution of controlled substances. In hospitals or other agencies that dispense controlled substances, the scheduled drugs are counted every 8–12 hr to account for each injectable, tablet, or other form of the drug. Any discrepancy in the number of drugs must be investigated and explained immediately.

### **DRUG DEVELOPMENT**

Drug development is a long and arduous process that can take from 7–12 years, and sometimes longer. The FDA has the responsibility for approving new drugs and monitoring drugs currently in use for adverse or toxic reactions. The development of a new drug is divided into the pre-FDA phase and the FDA phase. During the pre-FDA phase, a manufacturer conducts in vitro testing (testing in an artificial environment, such as a test tube) using animal and human cells to discover new drug compounds. This testing is followed by studies in live animals. The manufacturer then makes application to the FDA for Investigational New Drug (IND) status.

During the FDA phase, clinical (i.e., human) testing of the new drug begins. Clinical testing consists of three phases, with each phase involving a larger number of people (Fig. 1.2). In all phases the effects, both pharmacologic and



biologic, are studied. *Phase 1* involves 20–100 individuals who are healthy volunteers. This phase of testing is designed to see what the drug substance does to healthy tissue. If Phase 1 studies are successful, the testing moves to *Phase 2*, where the drug is given to people who have the disease or condition for which the drug is thought to be effective. If those results are positive for helping to reduce or eliminate the problem and adverse reactions are not too great, the testing progresses to *Phase 3*, in which the drug is given to large numbers of clients in medical research centers to provide information about adverse reactions. Phase 3 studies offer additional information on dosing and safety. Because of this extensive process, clinical trial studies can extend for many years.

### Concept Mastery Alert

A reason for a drug to enter a Phase 2 study would be to test the potential drug on clients with the disease the drug is designed to treat. A reason for a drug to enter a Phase 3 study is to determine any unanticipated effects.

A New Drug Application (NDA) is submitted after the investigation of the drug in Phases 1, 2, and 3 is complete and the drug is found to be safe and effective. With the NDA, the manufacturer submits all data collected concerning the drug during the clinical trials. A panel of experts, including pharmacologists, chemists, physicians, and other professionals, reviews the application and makes a recommendation to the FDA. The FDA then either approves or denies approval of the drug for use. This process can cost well over a billion dollars for a successful drug and take up to 12 years to be ready for marketing to the public (Lim, 2019). Although the cost of drugs is not covered in this textbook, it is of primary concern to many of the clients you will come into contact with during your career as a nurse.

After FDA approval, the company making the drug will give the new drug a brand name. This allows the company to sell the specific drug using this name for a limited time. The hope is that some of the research and development cost will be defrayed by the sales of this brand name drug. After the specified time, other companies may sell the drug using the generic name. The brand name is reserved for the company that first produced the specific drug substance.

After FDA approval, continued surveillance is done to ensure safety. Postmarketing surveillance (*Phase 4*) occurs after the manufacturer places the drug on the market. During this surveillance, an ongoing review of the drug occurs with particular attention given to adverse reactions. Health care providers are encouraged to help with this surveillance by reporting adverse effects of drugs to the FDA by using MedWatch (Box 1.1) or the Institute for Safe Medication Practices Medication Errors Reporting System.

### BOX 1.1 MedWatch and Reporting Adverse Events

- The FDA established a program called MedWatch for reporting safety and adverse events. Nurses or other health care providers can report observations of serious adverse drug effects or find safety information. Anyone can access the website (https://www.fda.gov/safety/medwatch-fdasafety-information-and-adverse-event-reporting-program) to obtain safety alerts on drugs, devices, or dietary supplements.
- The website provides a standardized form for reporting, which can be submitted electronically or downloaded, filled out, and mailed/faxed in to the program. Nurses play an important role in monitoring for adverse reactions. Therefore, it is important to submit reports, even if there is uncertainty about the cause–effect relationship. The FDA protects the identity of those who voluntarily report adverse reactions.
- The FDA considers serious adverse reactions those that may result in death, life-threatening illness, hospitalization, or disability or those that may require medical or surgical intervention. This form also is used to report an undesirable experience associated with the use of medical products (e.g., latex gloves, pacemakers, infusion pumps, anaphylaxis, blood, blood components).

### SPECIAL FOOD AND DRUG ADMINISTRATION PROGRAMS

Although it takes considerable time for most drugs to get FDA approval, the FDA has special programs to meet different needs. Examples of these special programs include:

- Orphan drug program
- Accelerated programs for urgent needs
- Risk Evaluation and Mitigation Strategies (REMS) program

### **Orphan Drug Program**

The Orphan Drug Act of 1983 was passed to encourage the development and marketing of products used to treat rare diseases. The act defines a rare disease as a condition affecting fewer than 200,000 individuals in the United States or a condition affecting more than 200,000 persons in the United States but for which the cost of producing and marketing a drug to treat the condition would not be recovered by sales of the drug.

The National Organization of Rare Disorders reports (2019) that there are more than 7000 rare disorders that affect approximately 30 million individuals. Examples of rare disorders include amyloidosis, Gaucher disease, and phenylketonuria.

The act provides for incentives such as research grants, protocol assistance by the FDA, and special tax credits to encourage manufacturers to develop orphan drugs. If the drug is approved, the manufacturer has 7 years of exclusive marketing rights. More than 1,700 new drugs and biologics have received FDA approval since the law was passed. Examples of orphan drugs include Velcade for multiple myeloma, Cerezyme—enzyme replacement therapy for Gaucher disease, and Valstar for the treatment of bladder cancer.

### **Accelerated Programs**

Accelerated approval of drugs is offered by the FDA as a means to make promising products for life-threatening diseases available on the market, based on preliminary evidence and before formal demonstration of client benefit. The approval that is granted is considered a "provisional approval," with a written commitment from the pharmaceutical company to complete clinical studies that formally demonstrate client benefit. If the drug continues to prove beneficial, the process of approval is accelerated.

Acquired immunodeficiency syndrome (AIDS) is an example of a disease that qualified as posing a significant health threat, and finding new drugs qualified for the accelerated program. When first discovered, AIDS was very devastating to the individuals affected and health agencies feared the danger the disease posed to public health. Therefore, the FDA and pharmaceutical companies worked together to shorten the IND approval process for drugs that showed promise in treating AIDS. This accelerated processs allowed primary health care providers to administer medications that indicated positive results in early Phase 1 and 2 clinical trials, rather than wait until final approval was granted. HIV is now viewed as a chronic disease, partly because of the efforts of accelerating the clinical trial process for drugs to treat AIDS.

The COVID-19 vaccine development is another example. Emergency use authorization was granted to two organizations (Pfizer-BioNTech and Moderna) within less than 1 year (Solis-Moreira, 2020). Owing to the pandemic nature of the SARS-CoV-2 pathogen, research and clinical trials were carried out in tandem and not sequentially, reducing the time needed to prepare the vaccines for market when international research and funding was provided (Solis-Moreira, 2020).

## Risk Evaluation and Mitigation Strategies

The **Risk Evaluation and Mitigation Strategies** (REMS) program is designed to monitor drugs that have higher risk to the client compared with benefit. To use a drug included in this program, there are specific educational requirements of the health care providers (prescribing and administering techniques) and education and monitoring for clients taking the drug. Therefore, only HCP-trained, enrolled, and certified providers may prescribe drugs with REMS restrictions. You can see the restrictions placed upon these drugs in a REMS program by visiting the brand name drug's website.

### HOW DRUGS WORK WITHIN THE BODY

Having learned about the naming and development of drugs, we turn to how drugs work. Once in the body, drugs act in certain ways or phases. Oral drugs go through three phases: the *pharmaceutic* phase, *pharmacokinetic* phase, and the *pharmacodynamic* phase (Fig. 1.3). Because liquid and parenteral drugs (drugs given by injection) are already in a fluid form they only go through the latter two phases, bypassing phase one entirely.

### **Pharmaceutic Phase**

In the **pharmaceutic phase**, the drug is dissolved. Drugs must be a soluble liquid to be absorbed by the body. Drugs that are liquid or drugs given by injection (parenteral drugs) are already dissolved and are absorbed quickly. A tablet or capsule (solid forms of a drug) goes through this phase in the gastrointestinal (GI) tract as it disintegrates into small particles and dissolves into the body fluids. Tablets that have an enteric coating and time-release capsules do not disintegrate until they reach the alkaline environment of the small intestine.



### PHARMACOLOGY IN PRACTICE

A client wants to know why their primary health care provider prescribes a liquid medication for an illness. How should the

nurse best explain the process to the client?
1. Easier to swallow

- 2 is absorbed faster by the body system
- Delays absorption until the liquid reaches the small intestine
- 4. Disintegrates into small pieces

### **Pharmacokinetic Phase**

**Pharmacokinetics** refers to the transportation activity of drugs in the body after administration. These activities include absorption, distribution, metabolism, and excretion. These phases can be broken down into subphases such as transport, first-pass effect during absorption, and half-life during excretion of the drug.

### Absorption

**Absorption** is the process by which a drug is made available for use in the body. This process involves moving the drug from the site of administration into the body fluids. It occurs after the solid form (e.g., a pill or tablet) of the drug dissolves or after the administration of an oral liquid or parenteral drug. During this process, the drug particles in the GI tract are moved into the body fluids. This movement can be accomplished in several ways:

• Active transport—cellular energy is used to move the drug from an area of low concentration to one of high concentration.



FIGURE 1.3 Drug activity within the body: pharmaceutic, pharmacokinetic, and pharmacodynamic phases.

- Passive transport—no cellular energy is used as the drug moves from an area of high concentration to an area of low concentration (small molecules diffuse across the cell membrane).
- Pinocytosis—cells engulf the drug particle (the cell forms a vesicle to transport the drug across the cell membrane and into the cell).

Several factors influence the rate of absorption, including the route of administration, the solubility of the drug, and specific conditions of the body's tissues. The most rapid route of drug absorption occurs when the drug is given by the intravenous (IV) route. When 100% of the drug given is available to the cells of the body, this is called **bioavailability**. Absorption occurs more slowly when the drug is administered orally, intramuscularly, or subcutaneously. This is because the complex membranes of the GI mucosal layers, muscle, and skin delay drug passage. Conditions in the body, such as *lipodystrophy* (the atrophy of subcutaneous tissue from repeated subcutaneous injections) inhibit absorption of a drug given in the affected site. This can occur when clients have to administer drugs repeatedly into the skin tissue, such as insulin administration for diabetes.

Another factor effecting absorption is the **first-pass effect**. When a drug is absorbed by the small intestine, it passes first into the liver before being released to circulate within the rest of the body. The liver metabolizes (or filters out) a significant amount of the drug before releasing it into the body. When the drug is released into the circulation from the liver, the remaining amount of active (or available) drug may not be enough to produce a therapeutic effect, and the client will need a higher dosage.

### **Distribution**

Once in the systemic circulation a drug is transported and distributed to various body tissues or target sites. **Distribution** of an absorbed drug in the body depends on:

- Blood flow—a drug is distributed quickly to areas with a large blood supply, such as the heart, liver, and kidneys. In other areas, such as the internal organs, skin, and muscle, distribution of the drug occurs more slowly.
- Solubility—the drug's ability to cross the cell membrane affects its distribution. Lipid-soluble drugs easily cross the cell membrane, whereas water-soluble drugs do not.
- Protein binding—when a drug travels through the blood, it comes into contact with proteins such as the plasma protein *albumin*. The drug can remain free in the circulation or bind to the protein. Only free drugs can produce a therapeutic effect. Drugs bound to protein are pharmacologically inactive. Only when the protein molecules release the drug can the drug diffuse into the tissues, interact with receptors, and produce a therapeutic effect. A drug is said to be highly protein bound when more than 80% of the circulating drug is bound to protein.

### Metabolism

**Metabolism**, also called *biotransformation*, is the process by which the body changes a drug to a more or less active form that can be excreted. A **metabolite** is the inactive form of the original drug. In some drugs, one or more of the metabolites may have some drug activity. Metabolites may undergo further metabolism or may be excreted from the body unchanged. Most drugs are metabolized by the liver, although the kidneys, lungs, plasma, and intestinal mucosa also aid in the metabolism of drugs.

### Excretion

Two important elements of elimination of drugs from the body are:

- Excretion—removal of drugs by the kidneys or the intestine.
- Half-life—the time required for the body to eliminate 50% of a drug.

After the liver renders drugs inactive, the circulatory system takes these products to the kidney where the inactive compounds are excreted from the body. Other drugs are eliminated in sweat, in breast milk, or by breath or by the GI tract through feces. Some drugs are excreted unchanged by the kidney without liver involvement; because this happens it can put undue stress on the kidney. Clients with kidney disease may require a dosage reduction and careful monitoring of kidney function. Children have immature kidney function and may require dosage reduction and kidney function tests during drug therapy. Similarly, older adults have diminished kidney function and require careful monitoring and lower dosages.

Half-life refers to the time required for the body to eliminate 50% of the drug. Knowledge of the half-life of a drug is important in planning the frequency of dosing. Drugs with a short half-life (2-4 hr) need to be administered frequently, whereas drugs with a long half-life (21-24 hr) require less frequent administration. For example, digoxin (Lanoxin) has a long half-life (36 hr) and requires once-daily dosing. However, aspirin has a short half-life and requires frequent dosing. It takes five to six half-lives to eliminate approximately 98% of a drug from the body? Although half-life is fairly stable, clients with liver or kidney disease may have problems excreting a drug. Difficulty in excreting a drug increases the half-life and the risk of toxicity, because these organs do not remove the substances and the drug remains in the body longer. Older clients or clients with impaired kidney or liver function require frequent diagnostic tests measuring renator hepatic function.

### Onset, Peak, and Duration—Drug Actions

Three additional factors influence the therapeutic action of a drug and in turn determine the timing of drug administration. These factors are important when considering how a drug acts in the body:

 Onset of action—time between administration of the drug and onset of its therapeutic effect.

- Peak concentration—when absorption rate equals the elimination rate (not always the time of peak response).
- Duration of action—length of time the drug produces a therapeutic effect.

These factors are taken into consideration when determining the dose schedule of a specific drug. This ensures that proper blood levels are maintained in the body for the drug to work properly.



### PHARMACOLOGY IN PRACTICE

A primary health care provider prescribes a lower drug dose to be administered every 6 hr instead of every 4 hr to a client with kidney disease.

Which of the following are reasons for such a prescriptive change? Select all that apply.

1. Disease prevents kidneys from excreting drug.

**INTERVENTIONS** 

- 2. Drug action is more effective when client is ill.
- 3. Client could exhibit blood level above therapeutic range.
- 4. Altered prescription reduces chance of accumulation of the drug.
- 5. Client could become drug dependent.

### **Pharmacodynamic Phase**

Pharmacodynamics is the study of the drug mechanisms that produce biochemical or physiologic changes in the body. **Pharmacodynamics** deals with the drug's action and effect in the body. After administration, most drugs enter the systemic circulation and expose almost all body tissues to possible effects of the drug. This exposure in all tissue causes the drug to produce more than one effect in the body.

- Primary effect—the desired or therapeutic effect on targeted tissue or organ.
- Secondary effects—all other effects, desirable or undesirable, produced by the drug.

Most drugs have an affinity for certain organs or tissues and exert their greatest action at the cellular level on those specific areas, which are called *target sites*. A drug exerts its action by one of two main mechanisms:

- Alteration in cellular function
- · Alteration in cellular environment

### **Alteration in Cellular Function**

Most drugs act on the body by altering cellular function. A drug cannot completely change the function of a cell, but it can alter the cell's function. A drug that alters cellular function can increase or decrease certain physiologic functions, such as increasing heart rate, decreasing blood pressure, or increasing urine output.

### **Receptor-Mediated Drug Action**

Many drugs act through drug–receptor interaction. The function of a cell is altered when a drug interacts with a receptor. This occurs when a drug molecule selectively joins with a reactive site—the receptor—on the surface of a cell. When a drug binds to and interacts with the receptor, a pharmacologic response occurs. This process is explained in greater depth in Units 4 and 5.

An *agonist* is a drug that binds with a receptor and stimulates the receptor to produce a therapeutic response; antidepressants are drugs that work this way. An *antagonist* is a drug that joins with receptors but does not stimulate the receptors. The therapeutic action in this case consists of blocking the receptor's function, an opioid reversal drug works in this way.

### **Receptor-Mediated Drug Effects**

The number of available receptor sites influences the effects of a drug. When only a few receptor sites are occupied, although many sites are available, the response will be small. When the drug dose is increased, more receptor sites are used, and the response increases. When only a few receptor sites are available, and once all the receptor sites are used, the response does not increase when more of the drug is administered. However, not all receptors on a cell need to be occupied for a drug to be effective. Some extremely potent drugs are effective even when the drug occupies few receptor sites.

### **Alteration in Cellular Environment**

Some drugs act on the body by changing the cellular environment, either physically or chemically. Physical changes in the cellular environment include changes in osmotic pressure, lubrication, absorption, or the conditions on the surface of the cell membrane.

An example of a drug that changes osmotic pressure is *mannitol*, which produces a change in the osmotic pressure in brain cells, causing a reduction in cerebral edema. A drug that acts by altering the cellular environment by lubrication is sunscreen. An example of a drug that acts by altering absorption is activated charcoal, which is administered orally to absorb a toxic chemical ingested into the GI tract. The stool softener docusate is an example of a drug that acts by altering the surface of the cellular memorane. Docusate has emulsifying and lubricating activity that lowers the surface tension in the cells of the bowel, permitting water and fats to enter the stool. This softens the fecal mass, allowing easier passage of the stool.

Chemical changes in the cellular environment include inactivation of cellular functions or alteration of the chemical components of body fluid, such as a change in the pH. For example, antacids neutralize gastric acidity in clients with peptic ulcers.

Other drugs, such as some anticancer drugs and some antibiotics, have as their main site of action the cell membrane and various cellular processes. They incorporate themselves into the normal metabolic processes of the cell and cause the formation of a defect, such as a weakened cell wall, which results in cell death, or reduces a needed energy substrate that leads to cell starvation and death.

### **Pharmacogenomics**

Most pharmacodynamic mechanisms deal with principles that affect each cell in the same way, whereas *pharmacogenomics* is the study of how people's responses to medications are variable because of individual genetic variation. The genetic makeup of a person can affect the pharmacodynamics of a drug. This discovery was made during the Human Genome Project when many scientists were able to determine the different components of the human genetic code. One example is the way some individuals respond to the drug warfarin. This is a drug taken to reduce the chance of blood clots and is a blood thinner. Clients with a specific gene duplication who take warfarin are more likely to bleed when taking the average dose of the drug. This pharmacological response to a genetic variation is discussed in Chapter 36.

*Pharmacogenetics* (a subcategory of the above) is the study of differences in body function due to genetic differences and how that impacts the creation of individualized drug therapy that allows for the best choice and dose of drugs (Saini et al., 2010).

# DRUG USE, PRÉGNANCY, AND

With the abundance of self-help information on the Internet, women of childbearing age are bombarded with a large amount of information regarding drug use, pregnancy, and lactation. In general, most drugs are contraindicated during pregnancy and lactation unless the potential benefits or taking the drug outweigh the risks to the fetus or the infant. Pregnant woman should not take any drug, legal or illegal, prescription or nonprescription, unless the drug is prescribed or recommended by the primary health care provider. Children born of mothers using addictive drugs, such as methamphetamine or oxycontin, often are born with a dependency to the drug used by the mother. Although promoted as a natural substance, herbal supplements can act like drugs, too. Women should not take an herbal supplement without discussing it first with the primary health care provider.

Smoking tobacco or drinking any type of alcoholic beverage carries risks and should be eliminated for the duration of pregnancy. Drinking alcohol is associated with risks of low birth weight, premature birth, and fetal alcohol syndrome. Inhalation of substances other than tobacco, such as electronic cigarettes or marijuana, have not been studied to the extent of making recommendations, yet most health care providers do not recommend use because of potential effects on the fetus.

Both expectant mothers and drug manufactures are concerned about the risk of causing birth defects in the developing fetus. The use of any medication (prescription or nonprescription) carries this risk, particularly during the first trimester (3 months), when the drug may have teratogenic effects. A **teratogen** is any substance that causes abnormal development of the fetus, often leading to severe deformation or fetal death. Drugs known to cause fetal abnormalities are classified as teratogens.

In 2015, requirements for prescribing information to health care professionals by manufacturers changed. Subheadings within the Pregnancy and Lactation subsections of drug labels such as *risk summary, clinical considerations*, and *data* were now required. The old system to assign a drug's risk during pregnancy and breastfeeding used the letter categories of A, B, C, D, and X to classify the amount of risk to the developing fetus; to date, the new classification system is still transitioning into place and in many monographs you will see both the old letter system and the new informational system used. Therefore, the older letter-based system is provided as reference for you in Appendix A.

The letter categories for drug labeling have been in use since the 1970s and were often misinterpreted as a grading system of risk. The new method provides explanations, based on available information, about the potential benefits and risks for the mother, the fetus, children who are breastfeeding, and women and men of reproductive age. The new system will be used as new drugs are introduced to the market and as older drugs are reviewed by the FDA; therefore, you will see the old system in this text and in drug information resources as well as the new categories as they are developed.

A number of drugs are excreted in breast milk. Therefore, if a mother is lactating (breastfeeding), some of the drug she is taking will travel through her to the infant or child via the breast milk to be ingested and absorbed. It is important for both mothers and nurses to know the potential of exposure to a breastfeeding child when the mother is taking a drug.

The National Library of Medicine provides a free online database with information on drugs and lactation called LactMed (http://www.ncbi.nlm.nih.gov/books/ NBK501922/). This website is geared to the health care practitioner and nursing mother and containg over 1,100 drug records. It includes information such as maternal levels in breast milk, infant levels in blood, and potential effects in breastfeeding infants. A pharmacist, Dr. Thomas Hale, from Texas Tech University has developed a system of lactation risk categories similar to that of the FDA pregnancy risk categories for drugs. Drugs are assigned an L1 to L5 risk according to the drug's transmission in breast milk and the effect it may have on the child. Hale's listing of certain drugs may differ from those published by organizations such as the American Academy of Pediatrics, yet it is a good starting point for discussion with mothers who are breastfeeding.

### **DRUG REACTIONS**

Drugs produce many reactions in the body beyond the intended reaction. The following sections discuss adverse drug reactions, allergic drug reactions, drug idiosyncrasy, drug tolerance, cumulative drug effect, and toxic reactions.

### Adverse Drug Reactions

Clients may experience one or more adverse reactions or side effects when they are given a drug. Adverse reactions are undesirable drug effects. **Adverse reactions** may be common or may occur infrequently. They may be mild, severe, or life-threatening. They may occur after the first dose, after a few doses, or after many doses. Often, an adverse reaction is unpredictable, although some drugs are known to cause certain adverse reactions in many clients. Often these reactions affect the GI system. For example, drugs used in treating cancer are very toxic and are known to produce adverse reactions in many clients receiving them. Other drugs produce adverse reactions in fewer clients. Some adverse reactions are predictable, but many adverse drug reactions occur without warning.

### NURSING ALERT

There are some adverse reactions that you will see with each client you care for in your role as a nurse. Other adverse reactions are so infrequent you may never see one. In this text we list both the common and unusual adverse reactions, because as a nurse you see many clients and the likelihood that you will care for a person experiencing a severe adverse reaction is much greater than it is for other types of health care providers. If you could avert a lasting complication or even a death through your knowledge of adverse reactions. It would be a wonderful accomplishment in your career.

Some texts use both the terms *side effects* and *adverse reactions*, using *side effects* to explain mild, common, and nontoxic reactions and *adverse reactions* to describe more severe and life-threatening reactions. For the purposes of this text and to avoid confusion, only the term *adverse reaction* is used, with the understanding that these reactions may be mild, severe, or life-threatening and will be defined as such.

### **Allergic Drug Reactions**

An **allergic reaction** is a **hypersensitive** response of the immune system. Allergy to a drug usually begins to occur when more than one dose of the drug has been given. On occasion, the nurse may observe an allergic reaction the first time a drug is given, because the client has been exposed to the drug in the past.

A drug allergy occurs because the individual's immune system responds to the drug as a foreign substance called an *antigen*. When the body responds to the drug as an antigen, a series of events occurs in an attempt to render the invader harmless. Lymphocytes respond by forming *antibodies* (protein substances that protect against antigens). Common allergic reactions occur when the individual's immune system responds aggressively to the antigen. Chemical mediators released during the allergic reaction produce symptoms ranging from mild to life-threatening.

Even a mild allergic reaction produces serious effects if it goes unnoticed and the drug is given again. Any indication of an allergic reaction is reported to the primary health care provider before the next dose of the drug is given. Serious allergic reactions require contacting the primary health care provider immediately, because emergency treatment may be necessary.

Some allergic reactions occur within minutes (even seconds) after the drug is given; others may be delayed for hours or days. Allergic reactions that occur immediately often are the most serious.

Allergic reactions are manifested by a variety of signs and symptoms observed by the nurse or reported by the client. Examples of some allergic symptoms include itching, various types of skin rashes, and hives (urticaria). Other symptoms include difficulty breathing, wheezing, cyanosis, a sudden loss of consciousness, and swelling of the eyes, lips, or tongue.

**Anaphylactic shock** is an extremely serious allergic drug reaction that usually occurs shortly after the administration of a drug to which the individual is sensitive. This type of allergic reaction requires immediate medical attention. Symptoms of anaphylactic shock are listed in Table 1.2.

An anaphylactic reaction should be considered if all or only some of these symptoms are present. Anaphylactic shock can be fatal if the symptoms are not identified and treated immediately. The treatment goal is to raise the blood pressure, improve breathing, restore cardiac function, and treat other symptoms as they occur. Epinephrine (adrenalin) may be given by subcutaneous injection in the upper extremity or thigh and may be followed by a continuous IV infusion. Hypotension and shock may be treated with fluids and vasopressors. Bronchodilators are given to relax the smooth muscles of the bronchial tubes. Antihistamines and corticosteroids may also be given to treat urticaria and angioedema (swelling). These are all drugs you will learn about in subsequent chapters of this book.

### TABLE 1.2 Symptoms of Anaphylactic Shock

BODY SYSTEM	SYMPTOMS
Respiratory	Bronchospasm Dyspnea (difficult breathing) Feeling of fullness in the throat Cough Wheezing
Cardiovascular	Extremely low blood pressure Tachycardia (heart rate >100 bpm) Palpitations Syncope (fainting) Cardiac arrest
Integumentary	Urticaria (hives) Angioedema Pruritus (itching) Sweating
Gastrointestinal	Nausea Vomiting Abdominal pain

Angioedema (angioneurotic edema) is another type of allergic drug reaction. It is manifested by the collection of fluid in subcutaneous tissues. Areas that are most commonly affected are the eyelids, lips, mouth, and throat, although other areas also may be affected. Angioedema can be dangerous when the mouth and throat are affected because the swelling may block the airway and asphyxia may occur. Difficulty in breathing and swelling in any area of the body are reported immediately to the primary health care provider.

### Drug Idiosyncrasy

**Drug idiosyncrasy** is a term used to describe any unusual or atypical reaction to a drug. It is any reaction that is different from the one normally expected from a specific drug and dose. For example, a client may be given a drug to help them sleep (e.g., a hypnotic). Instead of failing asleep, the client remains wide awake and shows signs of nervousness or excitement. This response is idiosyncratic because it is different from what one expects from this type of drug. Another client may receive the same drug and dose, fall asleep, and after 8 hr be difficult to awaken. This, too, is abnormal and describes an overresponse to the drug.

The cause of drug idiosyncrasy is not clear, although study in the science of genetics can give us insight into possible explanations. The inability to tolerate certain chemicals and drugs is believed to be because of a genetic deficiency. Pharmacogenetics, the study of ways that specific genes can enhance sensitivity or resistance to certain drugs, helps to explain some drug idiosyncrasies. A pharmacogenetic disorder is a genetically determined abnormal response to normal doses of a drug. This abnormal response occurs because of inherited traits that cause abnormal metabolism of drugs. For example, individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency have abnormal reactions to a number of drugs. These clients exhibit varying degrees of hemolysis (destruction of red blood cells) when these drugs are administered. More than 100 million people are affected by this disorder. Examples of drugs that cause hemolysis in clients with a G6PD deficiency include aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), and the sulfonamides.

### Drug Tolerance

**Drug tolerance** is a term used to describe a decreased response to a drug, requiring an increase in dosage to achieve the desired effect. Drug tolerance may develop when a client takes certain drugs, such as opioids and antianxiety drugs, for a long time. The individual who takes these drugs at home increases the dose when the expected drug effect does not occur. The development of drug tolerance is a sign of physical drug dependence. Drug tolerance may also occur in the hospitalized client. When the client begins to ask for the drug at more frequent intervals, the nurse needs to assess whether the dose is not adequate based on the disease process or whether the client is building a tolerance to the drug's effects.

### **Cumulative Drug Effect**

A **cumulative drug effect** may be seen especially in those people with liver or kidney disease because these organs are the major sites for the breakdown and excretion of most drugs. This drug effect occurs when the body is unable to metabolize and excrete one (normal) dose of a drug before the next dose is given. Thus, if a second dose of the drug is given, some drug from the first dose remains in the body. A cumulative drug effect can be serious because too much of the drug can accumulate in the body and lead to toxicity.

Clients with liver or kidney disease are usually given drugs with caution because a cumulative effect may occur. When the client is unable to excrete the drug at a normal rate, the drug accumulates in the body, causing a toxic reaction. Sometimes, the primary health care provider lowers the dose of the drug to prevent a toxic drug reaction.

### **Toxic Reactions**

Most drugs can produce toxic or harmful reactions if administered in large dosages or when blood concentration levels exceed the therapeutic level. Toxic levels build up when a drug is administered in doses that exceed the normal level or if the client's kidneys are not functioning properly and cannot excrete the drug. Some toxic effects are immediately visible; others may not be seen for weeks or months. Some drugs, such as lithium or digoxin, have a narrow margin of safety, even when given in recommended dosages. It is important to monitor these drugs closely to detect and avoid toxicity.

Drug toxicity can be reversible or irreversible, depending on the organs involved. Damage to the liver may be reversible because liver cells can regenerate. However, the anti-infective drug, streptomycin, may cause permanent hearing loss due to its toxic effect on the eighth cranial nerve. Sometimes drug toxicity can be reversed by administering another drug that acts as an antidote. For example, when too much opiate is taken, the drug naloxene (Narcan) may be given to counteract the effect.

When testing, carefully monitor the client's blood level of drug to ensure that the level remains within the therapeutic range. Any deviation should be reported to the primary health care provider. Because some drugs can cause toxic reactions even in recommended doses, you should be aware of the signs and symptoms of toxicity of commonly prescribed drugs.

### Minimizing Drug Reactions Through Pharmacogenomics

Drug developers are researching ways to target cell structures and selected cells to minimize reactions in other body tissues, thereby reducing or eliminating adverse reactions. Genetic specialists search for genetic variations associated with drug efficiency. One of the goals of pharmacogenomics is the creation of drugs that can be tailor-made for individuals, target specific cells in the body, and adapt to each person's own individual genetic makeup.

### **DRUG INTERACTIONS**

It is important when administering medications to be aware of the various drug interactions that can occur, especially *drug–drug interactions* and *drug–food interactions*. This section gives a brief overview of drug interactions. Specific drug–drug and drug–food interactions are discussed in subsequent drug specific chapters.

### **Drug–Drug Interactions**

A drug-drug interaction occurs when one drug interacts with or interferes with the action of another drug. For example, taking an antacid with oral tetracycline causes a decrease in the effectiveness of the tetracycline. The antacid chemically interacts with the tetracycline and impairs its absorption into the bloodstream, thus reducing the effectiveness of the tetracycline. Drug categories known to cause interactions with other drugs include oral anticoagulants, oral hypoglycemics, anti-infectives, antiarthythmics, cardiac glycosides, and alcohol. Drug-drug interactions can produce effects that are additive, synergistic, or antagonistic; these reactions are explained below.

### Additive Drug Reaction

An *additive drag reaction* occurs when the combined effect of two drugs is equal to the sum of each drug given alone. The equation 1 + 1 = 2 is sometimes used to illustrate the additive effect of drugs.

• Example—taking the drug heparin with alcohol will increase bleeding.

### **Synergistic Drug Reaction**

Drug *synergism* occurs when drugs interact with each other and produce an effect that is greater than the sum of their separate actions. The equation 1 + 1 = 3 may be used to illustrate synergism.

• Example—when a person takes both a hypnotic and alcohol. When alcohol is taken shortly before or after the hypnotic drug, the action of the hypnotic increases considerably. The individual experiences a drug effect that is greater than each drug taken alone. On occasion, the occurrence of a synergistic drug effect is serious and even fatal.

### Antagonistic Drug Reaction

An *antagonistic* drug reaction occurs when one drug interferes with the action of another, causing neutralization or a decrease in the effect of one of the drugs. The equation 1 - 1 = 0 may be used to illustrate antagonistic reactions.

• Example—protamine is a heparin antagonist. This means that the administration of protamine completely neutralizes the effects of heparin in the body and blood clotting will happen in the body.

### **Drug–Food Interactions**

When a drug is given orally, food may impair or enhance its absorption. A drug taken on an empty stomach is absorbed into the bloodstream more quickly than when the drug is taken with food in the stomach. Some drugs (e.g., captopril) must be taken on an empty stomach to achieve an optimal effect. Drugs that should be taken on an empty stomach are administered 1 hr before or 2 hr after meals.

Other drugs, especially drugs that irritate the stomach, result in nausea or vomiting, or cause epigastric distress, are best given with food or meals. This minimizes gastric irritation. The NSAIDs and salicylates are examples of drugs that are given with food to decrease epigastric distress.

Still other drugs combine with a food and may form an insoluble food–drug mixture. For example, when tetracycline is administered with dairy products, a drug–food mixture is formed that is not absorbable by the body. When a drug cannot be absorbed by the body, no pharmacologic effect occurs.

Components in foods may also prevent the medication from working. An enzyme in the human body that breaks down many drugs is prevented from working when people eat grapefruit.

### FACTORS INFLUENCING DRUG RESPONSE

Certain factors may influence drug response and are considered when the primary health care provider prescribes and the nurse administers a drug. These factors include age, weight, sex, disease, and route of administration.

### Age

The age of the client may influence the effects of a drug Infants and children usually require smaller doses of a drug than adults. Immature organ function, particularly of the liver and kidneys, can affect the ability of infants and young children to metabolize drugs. An infant's immature kidneys impair the elimination of drugs in the urine Liver function is not yet fully developed in infants and young children. Drugs metabolized by the liver may produce more intense effects for longer periods. Parents must be taught the potential problems associated with administering drugs to their children. For example, a safe dose of a nonprescription drug for a 4-year-old child may be dangerous for a 6-month-old infant.

Elderly clients may also require smaller doses, although this may depend on the type of drug administered. For example, the elderly client may be given the same dose of an antibiotic as a younger adult. However, the same older adult may require a smaller dose of a drug that depresses the central nervous system, such as an opioid. Changes that occur with aging affect the pharmacokinetics (absorption, distribution, metabolism, and excretion) of a drug. Any of these processes may be altered because of the physiologic changes that occur with aging. Table 1.3 summarizes the changes that occur with aging and their possible pharmacokinetic effects.

*Polypharmacy* is the taking of numerous drugs that can potentially react with one another. This is seen particularly in elderly clients who may have multiple chronic diseases; polypharmacy leads to an increase in the number of potential adverse reactions. Although multiple drug therapy is necessary to treat certain disease states, it always increases the possibility of adverse reactions. You need good assessment skills to detect any problems when monitoring the geriatric client's response to drug therapy.

### Weight

In general, standard dosages are based on a weight of approximately 77 kg (170 lb), which is calculated to be the average weight of men and women. A drug dose may sometimes be increased or decreased because the client's weight is significantly higher or lower than this average. With opioids, for example, higher- or lower-than-average dosages may be necessary, depending on the client's weight, to produce relief of pain.

TABLE 1.3 Factors Altering	Drug	Response in	n Children	and Older	Adults
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BODY SYSTEM CHANGES	CHILDREN/INFANTS	OLDER ADULTS
Gastric acidity	Higher pH—slower gastric emptying resulting in delayed absorption	Higher pH—slower gastric emptying resulting in delayed absorption
Skin changes	Less cutaneous fat, yet greater surface area—faster absorption of topical drugs	Decreased fat content—decreased absorption of transdermal drugs
Body water content	Increased body water content—greater dilution of drug in tissues	Decreased body water content—greater concentration of drug in tissues
Serum protein	Less protein—less protein binding creating more circulating drug	Less protein—less protein binding creating more circulating drug
Liver function	Immature function—increased half-life of drugs and less first-pass effect	Decreased blood flow to liver—delayed and decreased metabolism of drug
Kidney function	Immature kidney function—decreased elimination, potential for toxicity at lower drug levels	Decreased renal mass and glomerular filtration rate—increased serum levels of drugs

### Sex

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The sex of an individual may influence the action of some drugs. Women may require a smaller dose of some drugs than men. This is because many women are smaller and have a different body fat-to-water ratio than men.

### Disease

The presence of disease may influence the action of some drugs. Sometimes disease is an indication for not prescribing a drug or for reducing the dose of a certain drug. Both hepatic (liver) and renal (kidney) diseases can greatly affect drug response.

In liver disease, for example, the ability to metabolize or detoxify a specific type of drug may be impaired. If the average or normal dose of the drug is given, the liver may be unable to metabolize the drug at a normal rate. Consequently, the drug may be excreted from the body at a much slower rate than normal. The primary health care provider may then decide to prescribe a lower dose and lengthen the time between doses because liver function is abnormal.

Clients with kidney disease may exhibit drug toxicity and a longer duration of drug action. The dosage of drugs may be reduced to prevent the accumulation of toxic levels in the blood or further injury to the kidney.

### **Route of Administration**

The method used to get the drug into a person's body will affect the drug response. IV administration of a drug produces the most rapid drug action because the GI tract is completely bypassed. Next in order of time of action is the intramuscular (IM) route, followed by the subcutaneous (Subcut) route. Giving a drug orally usually produces the slowest drug action.

Some drugs can be given only by one route; for example, antacids are only given orally. Other drugs are available in oral and parenteral (IV, IM, Subcut) forms. The primary health care provider selects the route of administration based on many factors, including the desired rate of action. For example, the client with a severe cardiac problem may require IV administration of a drug that affects the heart. Another client with a mild cardiac problem may experience a good response to oral administration of the same drug.

### NURSING IMPLICATIONS WITH DRUG ACTIONS

Many factors can influence drug action. Consult appropriate references or the clinical pharmacist if there is any question about the dosage of a drug, whether other drugs the client is receiving will interfere with the drug being given, or whether the oral drug should or should not be given with food.

Drug reactions are potentially serious. Observe all clients for adverse drug reactions, drug idiosyncrasy, and evidence of drug tolerance (when applicable). It is important to report all drug reactions or any unusual drug effect to the primary health care provider.

Use good judgment when reporting adverse drug reactions to the primary health care provider. Accurate observation and evaluation of the circumstances are essential; record all observations in the client's record. If there is any question regarding the events that are occurring, withhold the drug and immediately contact the primary health care provider.

### HERBAL MEDICINE AND HEALTH CARE

Herbal medicine, herbalism, and herbal therapy are all names used for complementary/alternative therapies that use plants or herbs to treat various disorders. Individuals worldwide use herbal therapy and dietary supplements extensively. According to the World Health Organization, 80% of the world's population relies on herbs for a substantial part of their health care. Herbs have been used by virtually every culture in the world throughout history. For example, Hippocrates prescribed St. John's wort, currently a popular herbal remedy for depression Native Americans use plants such as coneflower, ginseng, and ginger for therapeutic purposes. Herbal therapy is part of the group of nontraditional therapies commonly known as complementary and alternative medicine (CAM).

### Complementary and Alternative Medicine

The National Center for Complementary and Integrative Health (NCCIH) is one of the 27 institutes and centers that make up the National Institutes of Health. The NCCIH explores complementary and alternative (or also called integrative) healing practices through scientific research. It also trains CAM scientists and disseminates the information gleaned from the research it conducts. Among the various purposes of the NCCIH is to evaluate the safety and efficacy of widely used natural products, such as herbal remedies and dietary and food supplements. The NCCIH is dedicated to developing programs and encouraging scientists to investigate CAM treatments that show promise. The NCCIH budget has steadily grown, reflecting the public's interest and need for CAM information that is based on rigorous scientific research.

The NCCIH defines CAM as a "group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine." Examples of complementary therapies are relaxation techniques, massage, aromatherapy, and healing touch. Complementary therapies are often used with traditional health care to "complement" conventional medicine. Alternative therapies, on the other hand, are therapies used in place of or instead of conventional or Western medicine. The term *complementary/alternative therapy* often is used as an umbrella term for many therapies from all over the world.



FIGURE 1.4 Example of herbal supplement labeling.

### Dietary Supplement Health and Education Act

In addition to vitamins and minerals, herbs are classified as dietary or nutritional supplements. *Nutritional* or *dietary substances* are terms used by the federal government to identify substances that are not regulated by the FDA but are purported to be effective in promoting health. Herbs are not sold and promoted in the United States as drugs. Therefore, they do not have to meet the same standards as drug and OTC medications for proof of safety and effectiveness and what the FDA calls "good manufacturing practices."

Because natural products cannot be patented in the United States, it is not profitable for drug manufacturers to spend the millions of dollars and the 7-12 years needed to study and develop these products as drugs. In 1994, the US government passed the Dietary Supplement Health and Education Act (DSHEA). This act defines substances such as herbs, vitamins, minerals, amino acids, and other natural substances as "dietary supplements." The act permits general health claims such as "improves memory" or "promotes regularity" as long as the label also has a disclaimer stating that the supplements are not approved by the FDA and are not intended to diagnose, treat, cure, or prevent any disease (Fig. 1.4). The claims must be truthful and not misleading and supported by scientific evidence. Some manufacturers have abused the law by making exaggerated claims, but the FDA has the power to enforce the law, which it has done, and these claims have decreased.

### Educating Clients About Herbs and Dietary Supplements

The use of herbs and dietary supplements to treat various disorders is common. At least 76% of the adult population in the United States use dietary supplements on a daily basis (CRN Survey, 2017). Herbs are used for various effects, such as boosting the immune system, treating depression, and promoting relaxation. Individuals are becoming more aware of the benefits of herbal therapies and dietary supplements. Advertisements, books, magazines, and Internet sites concerning these topics are prolific. People eager to cure or control various disorders take herbs, teas, megadoses of vitamins, and various other natural products. Although much information is available on dietary supplements and

herbal therapy, obtaining the correct information can be difficult at times. Medicinal herbs and dietary substances are available at supermarkets, pharmacies, health food stores, and specialty herb stores and through the Internet. The potential for misinformation abounds.

Because these substances are "natural products," many individuals incorrectly assume that they are without adverse effects. When any herbal remedy or dietary supplement is used, it should be reported to the nurse and the primary health care provider. Many of these natural substances have

### BOX 1.2 Teaching Points When Discussing Herbal Therapy

- Herbal preparations are not necessarily safe just because they are natural. Unlike prescription and OTC medicines, herbal products and supplements do not have to be tested to prove they work well and are safe before they are sold. Also, they may not be pure. They might contain other ingredients, such as plant pollen, that could make you sick. Sometimes they contain drugs that are not listed on the label, such as steroids or estrogens.
- If you have health problems, there may be an increased danger in taking herbal preparations. These conditions include blood-clotting problems, cancer, diabetes, an enlarged prostate gland, epilepsy, glaucoma, heart disease, high blood pressure, immune system problems, psychiatric problems, Parkinson disease, liver problems, stroke, and thyroid problems.
- If you are going to have surgery, be sure to tell your doctor if you use herbal products. Herbal products can cause problems with surgery, including bleeding and problems with anesthesia. Stop using herbal products at least 2 weeks before surgery, or sooner if your doctor recommends it.
- *Herbal products can change the way prescription and OTC drugs work.* Herbal health products or supplements can affect the way the body processes drugs. When this happens, your medicine may not work the way it should. This may mean the drugs are not absorbed at high-enough levels to help the conditions for which they are prescribed. This can cause serious problems. You should be especially cautious about using herbal health products or supplements if you take a drug in one of the following categories.

If you take any of these drugs, talk to your doctor before taking any type of herbal product or supplement.

- Drugs to treat depression, anxiety, or other psychiatric problems
- Antiseizure drugs
- Blood thinners
- Blood pressure medicine
- Heart medicine
- Drugs to treat diabetes
- Cancer drugs
- *Herbal products can cause other problems, too.* You should not take more than the recommended dose of any herbal health product or supplement. The problems that these products can cause are much more likely to occur if you take too much or take them for too long.

(*Karch's focus on nursing pharmacology* (5th ed.). 2011, Figure 1.3, p. 9.)

strong pharmacologic activity, and some may interact with prescription drugs or be toxic in the body. For example, *comfrey*, an herb that was once widely used to promote digestion, can cause liver damage. Although it may still be available in some areas, it is a dangerous herb and is not recommended for use as a supplement.

When obtaining the drug history, always question the client about the use of herbs, teas, vitamins, or other dietary supplements. Many clients consider herbs as natural and therefore safe. Some also neglect to report the use of an herbal tea as part of the health care regimen because they do not think of it as such. Explain to the client that just because an herbal supplement is labeled "natural," it does not mean the supplement is safe or without harmful effects. Herbal supplements can act the same way as drugs and can cause medical problems if not used correctly or if taken in large amounts. Box 1.2 identifies teaching points to consider when discussing the use of herbs and dietary supplements with clients.

Because herbal supplements are not regulated by the FDA, products lack standardization with regard to purity and potency. In addition, multiple ingredients in products and batch-to-batch variation make it difficult to determine

if reactions occur as a result of the herb itself. To assist with the identification of herb–drug interactions, report any potential interactions to the FDA through its MedWatch program (see Box 1.1). It is especially important to take special care when clients are taking any drugs with a narrow therapeutic index (the difference between the minimum therapeutic and minimum toxic drug concentrations is small—such as warfarin, a blood thinner) and herbal supplements. Because the absorption, metabolism, distribution, and elimination characteristics of most herbal products are poorly understood, much of the information on herb–drug interactions is speculative. Herb–drug interactions are sporadically reported and difficult to determine.

Although a complete discussion about the use of herbs is beyond the scope of this book, it is important to remember that the use of herbs and dietary supplements is commonplace in many areas of the country. To help you become more aware of herbal therapy and dietary supplements, Appendix D gives an overview of selected common herbs and dietary supplements featured in select chapters. In addition, "alerts" related to herbs and dietary supplements appear throughout this text to alert the learner to valuable information and precautions

### **KEY POINTS**

Pharmacology is the study of drugs and their action on living organisms.

■ Each drug has several names: a chemical name (chemical structure), a generic (nonproprietary, official—any company can use) name, and a trade (or brand) name.

Drugs are classified by use (such as anti-infectives) and categorized by their potential to be harmful (prescription, nonprescription, and controlled substances).

Controlled substances are restricted by a schedule system (C-I to V) and monitored by the DEA because they have higher abuse potential that can result in physical and/or psychological dependency.

■ The FDA has revised how drugs are categorized for potential benefits and risks for the mother, the fetus, children who are breastfeeding, and women and men of reproductive age.

■ The FDA has strict controls for research, study, and production of drug substances; these processes can take many years between substance discovery and actual marketing of a drug. There are special programs to speed this process for rare diseases or life-threatening conditions and provide for greater benefit than detriment from drug therapy. The three main phases of drug activity are pharmaceutic, pharmacokinetic, and pharmacodynamic.

■ Principles involved in pharmacokinetics include the following: absorption involves moving the drug from the site of administration; the drug is then distributed to tissues via the body circulation; metabolism changes the drug for use; and the drug is finally eliminated by the kidneys or made inactive by the liver and eliminated via the GI system.

Principles of pharmacodynamics involve the biochemical movement of drugs into a cell; by the receptors on cells; by altering the environment around the cell to gain entry.

Adverse reactions to drugs can range from minor GI distress to anaphylactic shock.

Drugs interact with many foods or other drugs, resulting in reactions less than or greater than when given alone.

Age, weight, sex, disease, and route of administration all influence a person's response to drug therapy.

Herbal preparations are not considered drugs, yet they should be considered part of a medical routine.

### CHAPTER REVIEW

### **Prepare for the NCLEX**

### RECALL THE FACTS

- 1. The best definition of *pharmacology* would be:
  - 1. the study of plants and living organisms
  - 2. making of chemical compounds for illnesses
  - 3. the study of drugs and their action on living organisms
  - 4. monitoring and accounting for substances used to make people well
- **2.** A client tells the nurse that he is taking Claritin. Which type of drug name is this?
  - 1. chemical
  - 2. official
  - 3. brand
  - 4. generic
- **3.** A new drug will be given to healthy volunteers to see what happens. In what phase of clinical trial is the drug being currently tested?
  - 1. Preclinical
  - 2. Phase 1
  - 3. Phase 2
  - 4. Phase 3
- **4.** A newly admitted client has a history of liver disease. In planning care, the nurse must consider that liver disease may result in a(n) \_\_\_\_\_.
  - 1. increase in the excretion rate of a drug
  - 2. impaired ability to metabolize or detoxify a drug
  - 3. need to increase the dosage of a drug
  - 4. decrease in the rate of drug absorption
- **5.** A client asks the nurse to define a hypersensitivity reaction. The nurse begins by telling the client that a hypersensitivity reaction is also called a(n) \_\_\_\_\_\_
  - 1. synergistic reaction
  - 2. antagonistic reaction
  - 3. drug idiosyncrasy
  - 4. allergic reaction
- **6.** In monitoring drug therapy, the nuse is aware that a synergistic drug effect may be defined as \_\_\_\_\_.
  - 1. an effect greater than the sum of the separate actions of two or more drugs
  - 2. an increase in the action of one of the two drugs being given
  - 3. a neutralizing drug effect
  - 4. a comprehensive drug effect

### ANALYZE THE FACTS

- **7.** \*A clienthas a rash and pruritus (itching). As the nurse, you suspect an allergic reaction and immediately assess him for other more serious symptoms. What question would be most important to ask the client?
  - 1. Are you having any difficulty breathing?
  - 2. Have you noticed any blood in your stool?
  - 3. Do you have a headache?
  - 4. Are you having difficulty with your vision?

- **8.** \*Under the Controlled Substances Act, schedule II to V drugs are typically accounted for in the health care setting. Which of the following drugs would the nurse least expect to be counted during change-of-shift duties?
  - 1. opioids
  - 2. antidiarrheals with codeine
  - 3. anabolic steroids
  - 4. heroin

### ALTERNATE-FORMAT QUESTIONS

- **9.** Arrange the following steps of pharmacokinetics correctly:
  - 1. absorption
  - 2. distribution
  - 3. elimination
  - 4. metabolism
- **10.** Identify the drug responses seen in children. **Select all that apply.** 
  - 1. pH of gastric acid is higher
  - 2. decreased body water
  - 3. less protein, less binding of drug
  - 4. greater amount of circulating drug

To check your answers, see Appendix F.

\*Indicates the question is directly linked to the NCLEX-PN test plan in Appendix C.

**WANT TO KNOW MORE?** A wide variety of resources are available to enhance your learning and understanding of this chapter.

- Visit for thePoint resources such as:
- NCLEX-Style Student Review Questions
- Journal Articles
- Dosage Calculations
- Drug Monographs
- Watch and Learn Videos
- Concepts in Action Animations
- The Study Guide to Accompany Introductory Clinical Pharmacology, 12th edition, sold separately, will help you review and apply essential content.
- **PropU** is available to help students prepare for the NCLEX-PN examination.