

THIRD CANADIAN EDITION

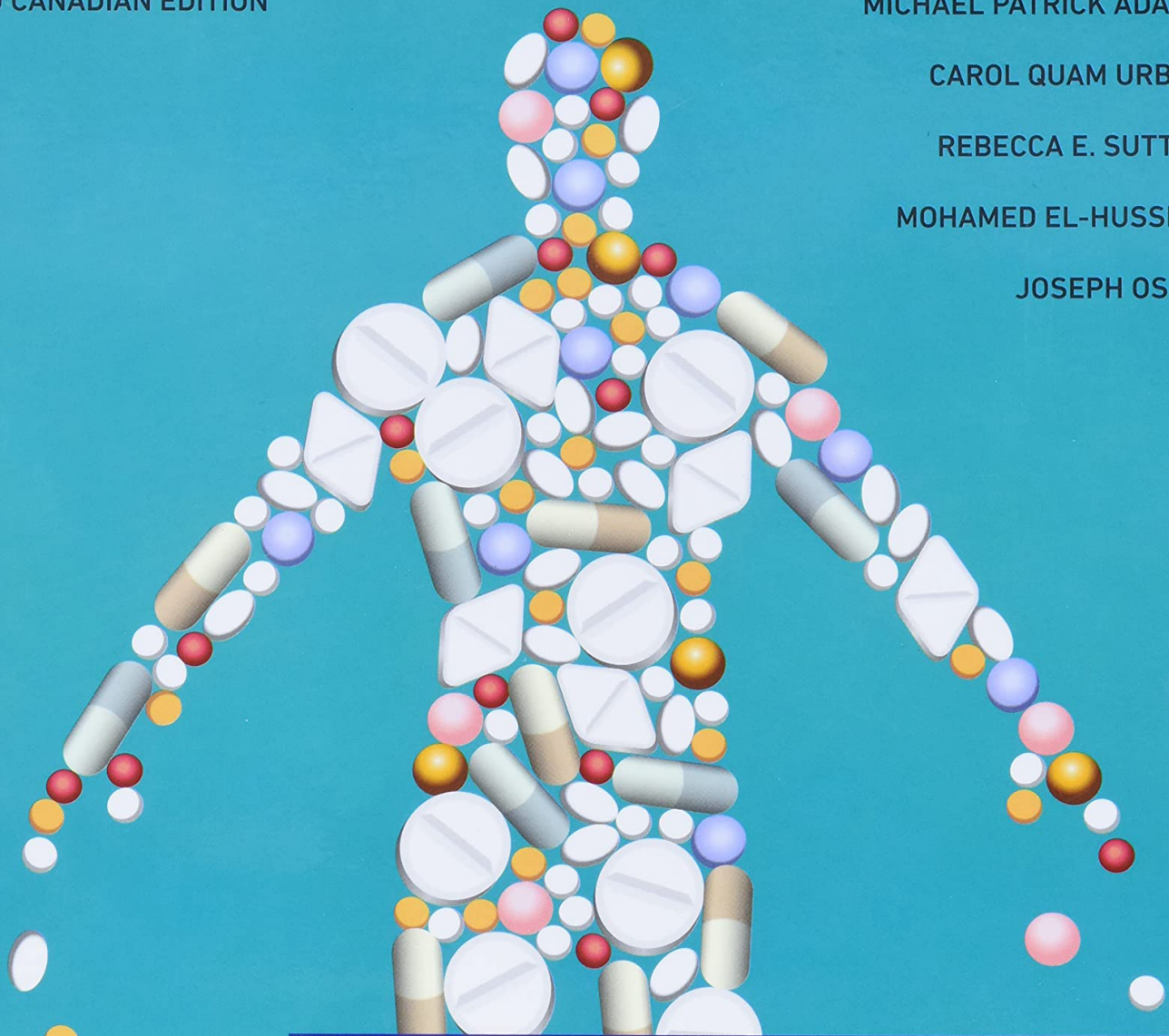
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PHARMACOLOGY FOR NURSES

A PATHOPHYSIOLOGICAL APPROACH



Pharmacology for Nurses

A Pathophysiological Approach

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Preface

When students are asked which subject in their nursing program is the most challenging, pharmacology and pathophysiology always appear near the top of the list. The study of pharmacology demands that students apply knowledge from a wide variety of the natural and applied sciences. The successful prediction of drug action requires a thorough knowledge of anatomy, physiology, chemistry, and pathology, as well as knowledge of the social sciences of psychology and sociology. Current knowledge of drug actions, mechanisms, interactions, and legislation is mandatory for nurses to provide safe and effective care to their clients in all healthcare settings. Lack of proper application of pharmacology can result in immediate and direct harm to the client; therefore, the stakes in learning pharmacotherapeutics in nursing are high.

Pharmacology can be made more understandable if the proper connections are made to knowledge learned in other disciplines; that's the impetus for starting every unit of the book with a review of the physiology of the related system or a discussion of the principles that inform pharmacotherapy. The vast majority of drugs in clinical practice are prescribed for specific diseases, yet many pharmacology texts fail to recognize the complex interrelationships between pharmacology and pathophysiology. When drugs are learned in isolation from their associated diseases or conditions, students have difficulty connecting pharmacotherapy to therapeutic goals and client wellness. The pathophysiology approach of this text gives the student a clearer picture of the importance of pharmacology to disease, and ultimately to client care. The approach and rationale of this text focus on a holistic perspective to client care, which clearly shows the benefits and limitations of pharmacotherapy in curing, managing symptoms, or

preventing illness. Although challenging, the study of pharmacology is truly a fascinating, lifelong journey.

The third Canadian edition continues the tradition of providing a unique Canadian perspective on pharmacotherapeutics, geared towards the education of Canadian undergraduate nursing students and their curriculum. During the editorial process, the text content was thoroughly reviewed and scrutinized by Canadian nurse educators and seasoned Canadian clinical pharmacists. The authors adapted the content of the U.S. edition of the text to fit the Canadian nursing context. The technical review process helped ensure accurate information on Canadian drug names, and their respective doses and routes of administration, including common Canadian Trade names for drugs. The review also highlighted drugs that are exclusively available and approved for use in Canada. Pregnancy categorizations of drugs were updated based on Canadian standards. Tables and illustrations to help students better assimilate pharmacotherapeutic concepts were also added to the respective chapters. We were intentional about adding recommendations for therapeutics driven by Canadian guidelines in the updated chapters. For example, research from Thrombosis Canada led to the addition of a section on direct oral anticoagulants (DOACs) in [Chapter 56](#). The *2017 Comprehensive Update of the Canadian Cardiovascular Society Guidelines for the Management of Heart Failure* were used to add updated content to [Chapter 54](#). Diabetes Canada clinical practice guidelines were integrated into [Chapter 28](#) to ensure its currency. The Canadian Cardiovascular Society's dyslipidemia guidelines were used to add the most recent drugs used to treat lipid disorders in [Chapter 49](#).

We believe that using the aforementioned guidelines ensures the currency and validity of the textbook. Finally, we also updated the NCLEX questions to reflect the current NCLEX test plan and blueprints.

Organization: A Body System and Disease Approach

Pharmacology for Nurses: A Pathophysiological Approach, third Canadian edition, is organized according to body systems (units) and diseases (chapters). This edition of the text has been expanded with new information. We have added more details to new chapters introduced in the second Canadian edition and included NCLEX Success Tips within each chapter to assist the student with making connections to the new NCLEX exam requirement for Canadian registered nurses. This component, that was introduced in the second Canadian edition, was well received and commended by students and faculty. The first chapter in each unit (except in Units 1, 2, and 3) provides a brief discussion of the physiology of the corresponding body system. Each chapter provides complete information on the drug classifications used to treat the diseases discussed in that chapter. Specially designed headings cue students to each classification discussion.

The pathophysiology approach clearly places the drugs in context in terms of how they are used therapeutically. The student is able to easily locate all relevant anatomy, physiology, pathology, and pharmacology in the same chapter in which the drugs are discussed. This approach provides the student with a clear view of the connections between pharmacology, pathophysiology, and the nursing care learned in other clinical courses.

NCLEX Success Tips

The third Canadian edition of *Pharmacology for Nurses: A Pathophysiological Approach* expands on more chapters to address the rapidly growing needs of students practising in the Canadian healthcare system. Before we started writing the text, we collected feedback from university professors, asking specifically about their experience using

other pharmacology texts and their perceptions of an ideal text. These professors shared some of the challenges their students face while taking a pharmacology course. An emerging but immediate need that echoed at a national level was the need to prepare Canadian nursing students to pass the NCLEX exam. Although students can take NCLEX courses after graduation or just before taking the exam, we believe that early introduction of NCLEX format and concepts will give the students ample time to understand and assimilate these concepts. Our textbook is the first nursing pharmacology text to incorporate NCLEX Success Tips.

We experienced challenges while trying to address all stakeholder concerns, as well as student needs, and at the same time keeping the text to a reasonable length. As a result, we reviewed several NCLEX texts and designed tips based on the latest NCLEX exam blueprints. We have presented the new content in a concise and succinct format and have used tables, figures, and illustrations to explain concepts.

Prototype Approach to Learning Drugs

The number of drugs available in clinical practice is staggering. To facilitate learning, we use prototype drugs and provide detailed introductions to the one or two most representative drugs in each classification. Students are less intimidated when they can focus their learning on one representative drug in each class. **Prototype Drug** boxes clearly describe these important medications. Within these boxes, the **actions and uses** of the drug are succinctly presented, including **administration alerts**, and **specific nursing responsibilities** that highlight vital information related to the administration of that drug and treatment of overdose and antidotes when known. **Pharmacokinetics** information regarding the absorption, distribution, metabolism, excretion, and half-life of drugs is included when known. **Adverse effects and interactions** are also included when necessary.

Focused Coverage of the Nursing Process

This text features a focused approach to the nursing process, which allows students to quickly find the content that is essential for safe and effective drug therapy. **Nursing Implications for Practice** sections appear within the discussion of each drug class. These sections discuss the major needs of the client, including general assessments, interventions, and client teaching for the class of drugs. Client education discussions provide students with the essential information that they need to convey to their clients. **Integrated rationales** for nursing actions help students to learn the reasoning that is key to the development of critical thinking skills.

Nursing Practice Application charts provide a succinct, easy-to-read view of the most commonly prescribed drug classes for the disease. Need-to-know nursing actions are presented in a format that reflects the “flow” of the nursing process: nursing assessment, pattern identification and potential nursing diagnoses, planning, interventions, client education and discharge planning, and evaluation. Rationales for interventions are included in parentheses. The Nursing Practice Application charts identify clearly the nursing actions that are most important. Some prototype drugs have important nursing actions that are specific to that drug; in these instances, we provide a Nursing Practice Application chart in the text devoted solely to the prototype drug.

Holistic Pharmacology

Our new edition examines pharmacology from a holistic perspective. The **Special Considerations** and **Lifespan Considerations** features present pharmacology and nursing issues related to **cultural, ethnic, age, gender,** and **psychosocial** aspects. These features remind students that a drug’s efficacy is affected as much by its pharmacokinetics as by the uniqueness of the client. In addition, **pediatric** and **geriatric** considerations are integrated throughout the text.

Natural Therapies features present a popular herbal or dietary supplement that may be considered along with conventional drugs. Although the authors do not recommend the use of these alternative treatments in lieu of conventional medicines, many clients use complementary and alternative therapies and the nurse must become familiar with how they affect client health. **Herb-drug interactions** are also included within the Prototype Drug boxes when relevant. Non-pharmacological methods for managing many diseases, including lifestyle and dietary modifications, are also integrated into the chapters.

Learning Pharmacology Through Visuals

For nearly all students, learning is a highly visual process. This text incorporates the generous use of artwork to illustrate and summarize key concepts. Pharmacotherapy illustrations provide students with a visual overview of a drug therapy process, showing specifically how the drug acts to counteract the effects of disease on the body.

The chapters on **Medication Incidents and Risk Reduction and Toxicology, Bioterrorism, and Emergency Preparedness** include important content on the promotion of client safety, management of medication incidents, and role of the nurse in situations that involve toxicity and biochemical emergencies.

Key Concepts outline what students should have learned in each chapter.

Scenarios with Critical Thinking Questions connect the student to a client at the end of most chapters. The student learns details about the client's health history and participates in critical thinking questions about the scenario. This allows for application of the knowledge obtained in the chapter.

NCLEX Practice Questions prepare students for course exams on chapter content and expose them to NCLEX-style questions. Answers and rationales are provided in [Appendix A](#).

A Note About Terminology

The term *healthcare provider* is used to denote the physician, nurse practitioner, registered nurse, or any other health professional who is legally authorized to prescribe drugs.

Acknowledgments

Authoring the third Canadian edition of this text has been a major undertaking made possible by the contributions of many individuals. First, we would like to acknowledge the efforts of the authors of the original Canadian edition and those of *Pharmacology: Connections to Nursing Practice* (4th U.S. Edition). Their work provided an excellent foundation for this text.

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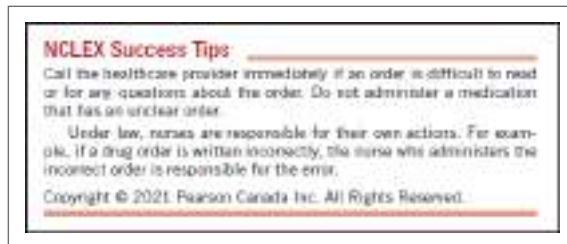
Mohamed El-Hussein

Joseph Osuji

Learning Pharmacology in Context

The vast majority of drugs are prescribed for specific diseases, yet many pharmacology texts fail to recognize the complex interrelationships between pharmacology and disease. Learning drugs in the context of their associated diseases will make it easier for you to connect pharmacotherapy to therapeutic goals and client wellness. The pathophysiology approach of this text gives you a clearer picture of the importance of pharmacology to disease and, ultimately, to nursing care.

NCLEX Success Tips. Addressing the need to prepare Canadian nursing students for the NCLEX exam, NCLEX Success Tips introduce the format and concepts of the NCLEX exam early enough to give students ample time to understand and assimilate them.



Disease and Body System Approach. The organization by body systems (units) and diseases (chapters) clearly places the drugs in context in terms of how they are used therapeutically. You can easily locate all relevant anatomy, physiology, pathophysiology, and pharmacology in the same chapter in which we present complete information for the drug classifications used to treat the diseases in each chapter. This organization builds the connection between pharmacology, pathophysiology, and the nursing care you learn in your clinical nursing courses.

UNIT 5 Pharmacology of Alterations in the Central Nervous System	
Chapter 13	Brief Review of the Central Nervous System 158
Chapter 16	Pharmacotherapy of Anxiety and Sleep Disorders 166
Chapter 17	Pharmacotherapy of Emotional and Mood Disorders 190
Chapter 18	Central Nervous System Stimulants and Pharmacotherapy of Attention Deficit and Hyperactive Disorders 200
Chapter 19	Pharmacotherapy of Psychoses 209
Chapter 20	Pharmacotherapy of Degenerative Diseases of the Nervous System 226
Chapter 21	Pharmacotherapy of Seizures 242
Chapter 22	Pharmacotherapy of Muscle Spasms and Spasticity 258
Chapter 23	Pharmacotherapy of Pain and Migraine 269
Chapter 24	Pharmacology of Local and General Anesthesia 290
Chapter 25	Pharmacotherapy in Substances of Abuse and Addiction 304

Prototype Approach and Prototype Drug Boxes. The number of drugs available in clinical practice is staggering. To help you learn them, we use a prototype approach in which we introduce the one or two most representative drugs in each classification in detail. It can be less intimidating to focus your learning on one representative drug in each class. **Prototype Drug** boxes clearly summarize these important medications, presenting:

- Actions and Uses
- Administration Alerts
- Pharmacokinetics (including onset of action, duration, half-life, and peak effect, when known)
- Adverse Effects and Interactions (with drugs, herbs, and food)

PROTOTYPE DRUG	Bethanechol (Duvoid)
<p>Actions and uses: Bethanechol is a direct-acting cholinergic that interacts with muscarinic receptors to cause actions typical of parasympathetic stimulation. Its effects are most noted in the digestive and urinary tracts, where it will stimulate smooth muscle contraction. These actions are useful in increasing smooth muscle tone and muscular contractions in the GI tract following general anesthesia. In addition, it is used to treat non-obstructive urinary retention in clients with atony of the bladder.</p>	

Providing a Nursing Focus

Once you understand how a drug works on the body—that is, its actions, therapeutic effects, potential side effects and interactions, and more—you begin to understand the “why” of the interventions you will take as a nurse. Each chapter guides you to the content that is essential in order for you to provide safe and effective drug therapy.

Nursing Implications for Practice appear within each drug class section and discuss the major needs of the client, including:

- General Assessments
- Interventions
- Lifespan Considerations
- Client Education for all drugs in that classification, when applicable

Nursing Implications for Practice

The role of the nurse in dopaminergic therapy involves careful monitoring of the client's condition and providing education as it relates to the prescribed drug regimen. Prior to the initiation of drug therapy, the client's health history should be taken. Those with narrow-angle glaucoma, undiagnosed skin lesions, or history of hypersensitivity should not take dopaminergic agents. Dopaminergics should be used cautiously in clients with severe cardiac, renal, liver, or endocrine diseases; mood disorders; or a history of seizures or ulcers and in those who are pregnant or lactating. Initial lab testing should include a complete blood count and liver and renal function studies. These tests should be obtained throughout the treatment regimen. Baseline information should include vital signs (especially blood pressure), mental status, and symptoms of Parkinson's disease. Lastly, all other medications taken by the client should be fully evaluated for compatibility with dopaminergic agonists.

During initial treatment, blood pressure, pulse, and respirations should be closely monitored because these drugs may cause hypotension and tachycardia. Additional lab testing for diabetes and acromegaly should be done if the client is expected to take the drug long term. The nurse should especially monitor clients for excessive daytime sleepiness, eye twitching, involuntary movements, hand tremors, fatigue, anxiety, mood changes, confusion, agitation, nausea, vomiting, anorexia, dry mouth, and constipation. Muscle twitching and mood changes may indicate toxicity and should be reported at once. The nurse may need to assist clients with drug administration and activities of daily living, including ambulation, at least initially. It is normal for the client's urine and perspiration to darken in colour. Client education as it relates to dopaminergic

Nursing Practice Application charts present need-to-know nursing actions in the nursing process—assessment, nursing diagnoses, planning, implementation with interventions and rationales, evaluation—and include client teaching and discharge planning.

CONNECTIONS Cultural Considerations

■ Ethnic Considerations in Acetaminophen Metabolism

Certain ethnic populations, including Asians, Africans, and Saudis, have higher rates of an enzyme deficiency that affects how their body metabolizes certain drugs. More than 200 million people worldwide are believed to have a hereditary deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD). Clients with G6PD deficiency are at risk for developing hemolysis after ingestion of certain drugs, including acetaminophen. Conflicting data exist on whether therapeutic dosages of acetaminophen can cause hemolysis in these clients. However, because acetaminophen is one of the most common drugs ingested in intentional overdoses, healthcare providers should recommend that clients with G6PD deficiency avoid this drug.

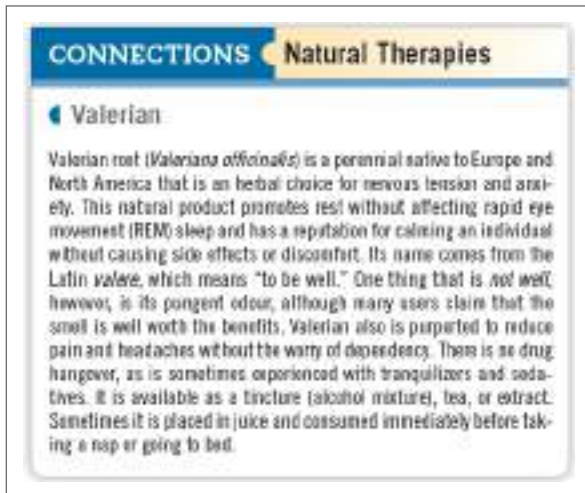
Lifespan Considerations boxes specifically address client care issues across the lifespan.

CONNECTIONS Lifespan Considerations

■ Dietary Supplements and the Older Adult

Can dietary supplements improve the health of older adults? A growing body of evidence is showing that the use of supplements can positively influence seniors' health. Dietary supplements have been successfully used to enhance older adults' immune systems, reduce short-term memory loss, lessen the risks of Alzheimer's disease, and improve overall health. Nutritional deficiencies greatly increase with age, and supplements help to prevent or eliminate these deficiencies in older adults. In addition, some research has shown that older adults who have low levels of folate and vitamin B₁₂ have an increased risk for developing Alzheimer's disease. The nurse should assess the need for such supplements in all older adults. However, the nurse should be aware that herbal and dietary supplements can be expensive, therefore, supplements should not automatically be included in treatment plans. In addition, older adults should be educated as to the risks of megavitamin therapy.

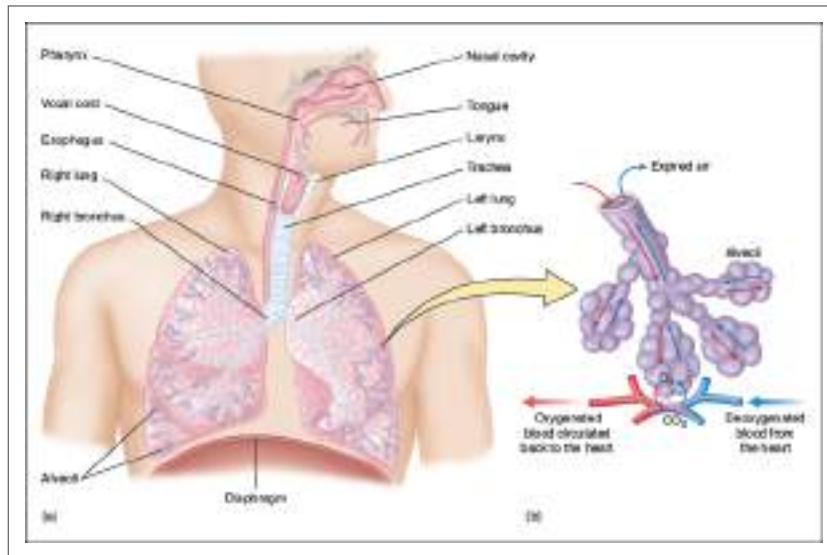
Natural Therapies boxes present popular herbal or dietary supplements that clients may use along with conventional drugs. As a nurse, you need to assess clients to see if they are using any natural remedies that may have interactions with medications they are taking.



Teaching Through Visuals

For nearly all students, learning is a highly visual process. Therefore, we use numerous visuals to help you review the anatomy and physiology of body systems as well as understand the principles of drug action on the body.

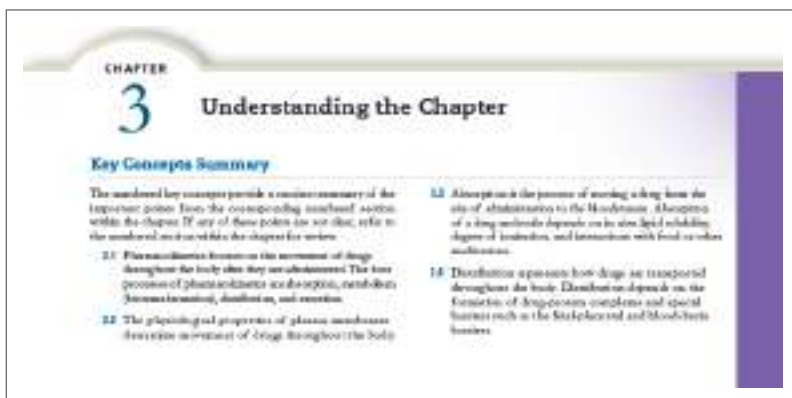
Vivid and Colourful Illustrations help you to review specific anatomy, physiology, and pathophysiology for a body system and better understand the impact of disease on that system.



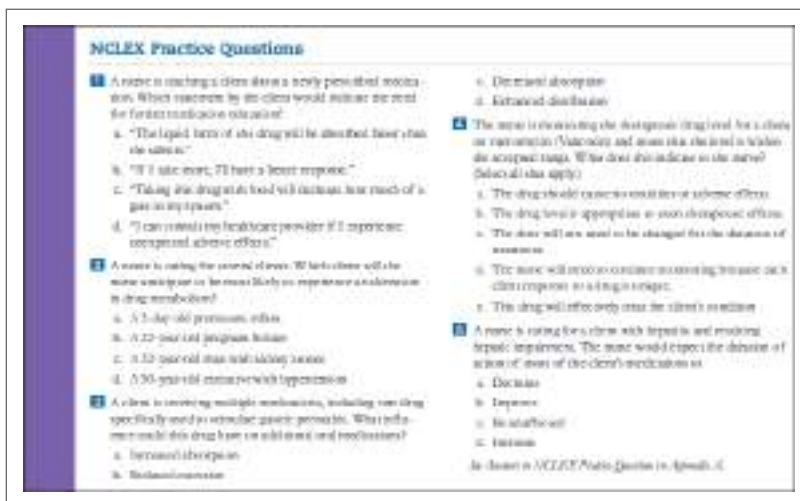
Putting It All Together

The tools at the end of each chapter and on **MyLab Nursing** help you to test your understanding of the drugs and nursing care presented in that chapter. Using these tools will help you to succeed in your pharmacology course, in the clinical setting, on the NCLEX exam, and ultimately in your professional nursing practice.

Key Concepts Summary provides expanded summaries of concepts that correlate to sections within the chapter. You can use this succinct summary to ensure that you understand the concepts before moving on to the next chapter. The numbering of these concepts helps you to easily locate that section within the chapter if you need further review.



NCLEX Practice Questions allow you to test your knowledge. Answers are available in [Appendix A](#) at the end of your text. Selected questions are also available for use in class with our Learning Catalytics tool.



Critical Thinking Questions help you to apply the essential components of nursing care through case-based scenarios. [Appendix B](#) provides answers to these questions.

Critical Thinking Questions

1. What is the difference between therapeutic classification and pharmacological classification?
2. What classification is a barbiturate? Macrolide? Birth control pills? Levatives? Folic acid antagonist? Antianginal agent?
3. What is a prototype drug, and what advantages does a prototype approach to studying pharmacology offer?
4. Why do nurses need to know all of this pharmacology?

See Answers to Critical Thinking Questions in Appendix B.

Chapter 1


Introduction to Pharmacology and Drug Regulations in Canada


Introduction to Pharmacology and Drug Regulations in Canada




Chapter Outline


Pharmacology: The Study of Medicines 


Pharmacology and Therapeutics 


Classification of Therapeutic Agents as Drugs, Biologics,
or Natural Health Products 

Prescription and Over-the-Counter Drugs 

Drug Regulations and Standards 

Federal Drug Legislation 

Approval Process for Prescription Drugs 

Pricing and Access to Prescription Drugs Across
Canada 



Learning Outcomes

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

1. Define pharmacology.
2. Discuss the interdisciplinary nature of pharmacology.
3. Compare and contrast therapeutics and pharmacology.
4. Compare and contrast conventional drugs, biologics, and natural health products.

5. Identify the advantages and disadvantages of prescription and over-the-counter (OTC) drugs.
6. Identify key Canadian drug regulations that help to ensure the safety and efficacy of medications.
7. Discuss the role of Health Canada and the Health Products and Food Branch (HPFB) of Health Canada and its Therapeutic Products Directorate in the drug approval process.
8. Describe the stages of approval for therapeutic and biologic drugs in Canada.

Key Terms

biologics, 2

clinical trials, 4

Compendium of Pharmaceuticals and Specialties (CPS), 5

complementary and alternative therapies, 2

drug, 2

Drug Identification Number (DIN), 4

Drug Product Database, 5

formulary, 5

Health Canada, 3

medication, 2

natural health products (NHPs), 2

New Drug Submission (NDS), 4

Notice of Compliance (NOC), 4

patent protection, 4

pharmacology, 2

pharmacotherapy (pharmacotherapeutics), 2

preclinical investigation, 4

Special Access Program (SAP), 6

therapeutics, 2

More drugs are being prescribed to consumers than ever before. About 500 million prescriptions are dispensed each year in Canada. According to Statistics Canada, prescription medications are the second most costly component of Canadian healthcare expenditure, accounting for almost 14% (\$29 billion) each year. Laws govern all aspects of the drug approval, labelling, marketing, manufacturing, and distribution process. The purpose of this chapter is to introduce the subject of pharmacology and to emphasize the role of government in ensuring that drugs, herbals, and other natural alternatives are safe and effective for public use.

Pharmacology: The Study of Medicines

1.1 Pharmacology is the study of medicines. It includes how drugs are administered and how the body responds.

The word **pharmacology** ^① is derived from two Greek words: *pharmakon*, which means “medicine, drug,” and *logos*, which means “study.” Thus, pharmacology is most simply defined as the study of medicines.

Pharmacology is an expansive subject ranging from understanding how drugs are administered, to where they travel in the body, to the actual responses produced. To learn the discipline well, nursing students need a firm understanding of concepts from various foundation areas such as anatomy and physiology, chemistry, microbiology, and pathophysiology.

More than 11 000 brand name, generic, and combination agents are currently available. Each has its own characteristic set of therapeutic applications, interactions, side effects, and mechanisms of action. Many drugs are prescribed for more than one disease, and most produce multiple effects on the body. Further complicating the study of pharmacology is the fact that drugs may elicit different responses depending on individual client factors such as age, gender, body mass, health status, and genetics. Indeed, learning the applications of existing medications and staying current with new drugs introduced every year is an enormous challenge for the nurse. The task, however, is a critical one for both the client and the healthcare provider. If used properly, drugs can dramatically improve quality of life, but the consequences of improper use of drugs can be devastating.

Pharmacology and Therapeutics

1.2 The fields of pharmacology and therapeutics are closely connected. Pharmacotherapy is the application of drugs to prevent disease and ease suffering.

A thorough study of pharmacology is important to healthcare providers who prescribe or administer drugs. Although federal and provincial laws sometimes limit the kinds of drugs marketed and the methods used to dispense them, *all* nurses are directly involved with client care and are active in educating, managing, and monitoring the proper use of drugs. This applies not only for nurses in clinics, hospitals, and home healthcare settings, but also for nurses who teach and for new students entering the nursing profession. In all of these cases, a thorough knowledge of pharmacology is necessary for them to perform their duties. As nursing students progress toward their chosen specialty, pharmacology is at the core of client care and is integrated into every step of the nursing process. As new drugs and research findings emerge, nurses are challenged to evaluate the information and incorporate relevant knowledge into evidence-based practice.

Another important area of study for the nurse, sometimes difficult to distinguish from pharmacology, is the study of therapeutics. Therapeutics is slightly different from the field of pharmacology, although the disciplines are closely connected. **Therapeutics** is the branch of medicine concerned with the prevention of disease and treatment of suffering. **Pharmacotherapy**, or **pharmacotherapeutics**, is the administration of drugs for the purpose of disease prevention or treatment and relief of suffering. Drugs are just one of many therapies available to the nurse for preventing or alleviating human suffering.

Classification of Therapeutic Agents as Drugs, Biologics, or Natural Health Products

1.3 Therapeutic agents may be classified as traditional drugs, biologics, or natural health products.

Substances applied for therapeutic purposes fall into one of the following three general categories:

- Drugs or medications
- Biologics
- Natural health products

A **drug** is a chemical agent capable of producing biological responses within the body. These responses may be desirable (therapeutic) or undesirable (adverse). A drug that is considered medically therapeutic is commonly referred to as a **medication**. Because drugs are defined so broadly, it is necessary to separate them from other substances that can alter the body's biological activities, such as foods, household products, and cosmetics. Agents such as antiperspirants, sunscreens, toothpastes, and shampoos might alter the body's biological activities, but they are not considered drugs or medications. Sometimes it is not clear whether a substance is a medication. For example, alcohol (beer, red wine) may be considered medically therapeutic when used in small amounts for cardiovascular effects, yet not be therapeutic when used in excess.

While most modern drugs are synthesized in a laboratory, **biologics** are agents naturally produced in animal cells, by microorganisms, or by the

body itself. Examples of biologics include hormones, monoclonal antibodies, natural blood products and components, interferon, and vaccines. Biologics are used to treat or prevent a wide variety of illnesses and conditions.

Other therapeutic approaches include **natural health products (NHPs)** and complementary and alternative therapies. NHPs may include natural plant extracts, herbals, vitamins, minerals, and dietary supplements. NHPs are discussed in detail in **Chapter 11**. **Complementary and alternative therapies** include therapies such as acupuncture, hypnosis, biofeedback, and massage. Because of their growing popularity, herbal and alternative therapies are featured throughout this text. It is important to ensure that information related to home herbal remedies is shared with medical professionals, to make certain that the client does not receive two different forms of the same drug or drugs that may counteract the home remedy.

The nurse should support the client by facilitating an open discussion on the client's intent to use herbal remedy with the physician. This will make the client feel involved in the decisions related to his or her care. Remind the client that the herbs may interfere with current medications that he or she is taking.

NCLEX Success Tips

The nurse should ensure that pregnant women avoid any medication unless their physician instructs them to use it. This includes herbal remedies because their effects on the fetus have not been identified.

Prescription and Over-the-Counter Drugs

1.4 Drugs are available by prescription or over the counter.
Prescription drugs require an order from a healthcare provider.

Legal drugs are obtained either by a prescription or over the counter (OTC). There are major differences between the two dispensing methods. To obtain prescription drugs, a qualified healthcare provider must give an order authorizing the client to receive the drug. Prescription drugs are considered potentially addictive or too harmful for self-administration. In some cases, they are used to treat conditions too complex for self-diagnosis by the consumer, or the drug may require a skilled nurse or healthcare provider to administer it. The advantages to requiring an authorization are numerous. The healthcare provider has an opportunity to examine the client and determine a specific diagnosis. The healthcare provider can maximize therapy by ordering the proper drug for the client's condition and controlling the amount and frequency of drug to be dispensed. In addition, the healthcare provider has an opportunity to teach the client the proper use of the drug and what side effects to expect. In a few instances, a high margin of safety observed over many years can prompt a change in the status of a drug from prescription to OTC.

NCLEX Success Tips

Call the healthcare provider immediately if an order is difficult to read or for any questions about the order. Do not administer a medication that has an unclear order.

Under law, nurses are responsible for their own actions. For example, if a drug order is written incorrectly, the nurse who administers the incorrect order is responsible for the error.

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In contrast to prescription drugs, OTC drugs do not require a prescription. In most cases, clients may treat themselves safely if they carefully follow instructions included with the medication. If they do not follow these guidelines, OTC drugs can have serious adverse effects.

NCLEX Success Tips

Older adults commonly have multiple healthcare provider. The client needs to inform every healthcare provider about all the medications being prescribed by all of them.

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Clients prefer to take OTC drugs for many reasons. They may be obtained more easily than prescription drugs because they do not require an order from a healthcare provider. A key point to remember is that no drug is without risk; if clients do not follow the guidelines on the label, serious adverse effects may result.

No appointment with a physician is required, thus saving time and money. Without the assistance of a healthcare provider, however, choosing the proper drug for a specific problem can be challenging for an individual. OTC drugs may react with foods, herbal products, prescription

medications, or other OTC drugs. Individuals may not be aware that some drugs can impair their ability to function safely. Self-treatment is sometimes ineffective, and the potential for harm may increase if the disease is allowed to progress.

Drug Regulations and Standards

1.5 Drug regulations were created to protect the public from drug misuse and to assume continuous evaluation of safety and effectiveness.

Until the 19th century, there were few standards or guidelines to protect the public from drug misuse. The archives of drug regulatory agencies are filled with examples of early medicines, including rattlesnake oil for rheumatism; epilepsy treatment for spasms, hysteria, and alcoholism; and fat reducers for a slender, healthy figure. Many of these early concoctions proved ineffective, though harmless. At their worst, some contained hazardous levels of dangerous or addictive substances. It became quite clear that drug regulations were needed to protect the public.

Federal Drug Legislation

1.6 The regulatory agency responsible for ensuring that drugs are safe and effective is the Therapeutic Products Directorate of the Health Products and Food Branch of Health Canada.

The mandate for Health Products and Food Branch (HPFB) of Health Canada [®] “mandate is to manage the health-related risks and benefits of health products and food by minimizing health-risk factors to Canadians while maximizing the **safety** provided by the **regulatory** system for health products and food.” The HPFB regulates the use of therapeutic products through directorates, as shown in [Figure 1.1](#). The Therapeutic Products Directorate (TPD) authorizes marketing of a pharmaceutical drug or medical device once a manufacturer presents sufficient scientific evidence of the product’s safety, efficacy, and quality as required by the Food and Drugs Act and Regulations. The Biologics and Genetic Therapies Directorate (BGTD) regulates biologic drugs (drugs derived from living sources), radiopharmaceuticals, and genetic therapies. Products regulated by the BGTD include blood products, vaccines, tissues, organs, and gene therapy products. The Natural and Non-prescription Health Products Directorate (NNHPD) is the regulating authority for natural health products for sale in Canada. Natural health products and their regulation are presented in [Chapter 11](#).

Figure 1.1 The governance structure for therapeutic products in Canada.

