Instructor’s

Resource Manual

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**Pharmacology for Nurses**

**A Pathophysiological Approach**

Second Canadian Edition

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**Chapter 1 Introduction to Pharmacology: Drug Regulation and Approval in Canada**

**Learning Outcomes:**

1. Define pharmacology.

Suggested Classroom Activity: Make a time line with students to demonstrate how the science of pharmacology has progressed in the past 200 years.

Suggested Clinical Activity: Discuss future developments in pharmacology with the pharmacist at a clinical site.

2. Discuss the interdisciplinary nature of pharmacology.

Suggested Classroom Activity: Using the examples of water, vitamin C, and natural hormones, discuss how a client may be confused about the difference between a substance for everyday use or one that naturally occurs in the body, and how these change when used in drug therapy.

Suggested Clinical Activity: Have students ask a nurse at a clinical site for an example of how pharmacotherapy made a difference in a client’s health.

3. Compare and contrast therapeutics and pharmacology.

Suggested Classroom Activity: Go to Health Canada website. Engage students in using the website to search for various drugs. Use the FAQ link to demonstrate how to stay updated on new drugs.

Suggested Clinical Activity: Have students compare and contrast medication therapy used for clients who have the same disease state, but are being treated with different drugs. Compare the drug’s pharmacologic and therapeutic classifications.

4. Compare and contrast conventional drugs, biologics, and natural health products. Suggested

Classroom Activity: Have students use the textbook to locate a prototype drug. Discuss how it is easily identifiable and what important nursing considerations are listed for each prototype.

Suggested Clinical Activity: Have students look at a medication administration record for an assigned client. Compare which drugs are prototypes and which are not. Students could also discuss how different or similar the drug is to the prototype.

5. Identify the advantages and disadvantages of prescription and over-the-counter (OTC) drugs.

Suggested Classroom Activity: Have students look at popular generics such as acetaminophen, aspirin, and ibuprofen. Have them identify possible trade names that are popular for these drugs. Then look at which products may represent a combination of drugs.

Suggested Clinical Activity: Have students take a drug history from a client. Discuss if the clients identify their medications by generic or trade names. Have students discuss how this could lead to possible medication errors.

6. Identify key Canadian drug regulations that help to ensure the safety and efficacy of medications.

Suggested Classroom Activity: Using Internet pharmacy sites, compare and contrast the differences between prices for trade and generic drugs.

Suggest Clinical Activity: Have students interview a pharmacist regarding the changes that occur when a pharmaceutical company’s period of exclusivity for the manufacture of a drug expires.

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.

Suggested Classroom Activity: Give examples of drugs that may be available to the client in both trade and generic names. Suggestions include ibuprofen, loratadine, and pseudoephedrine. Discuss what could change the bioavailability of the drug.

Suggested Classroom Activity: Have the student role-play a scene in which a client asks a nurse if generic substitutions are safe, and how the nurse would respond. Role-play another scene where the client asks the nurse about using an overseas Internet pharmacy.

Suggested Clinical Activity: Have students interview a hospital pharmacist to find out what the law in their state is regarding substitution of generic drugs. Ask how the pharmacist discusses the use of generic drugs with the prescriber.

Suggested Clinical Activity: Have students interview a neighborhood pharmacist about insurance reimbursement for generic drugs.

8. Describe the stages of approval for therapeutic and biologic drugs in Canada.

Suggested Classroom Activity: Go to Health Canada website. Engage students in using the website to explore the stages of approval for therapeutic and biologic drugs in Canada. Ask students to compare it with the process of approving none therapeutic products

Suggested Clinical Activity: Have students explore if any clinical trials are being conducted on the facility where they are assigned. Have students investigate when the drugs used in clinical trials will be available for use

**Key Concepts**

1. Pharmacology, now a key aspect of nursing care, started with early man using plants and herbs to relieve disease symptoms. Many early remedies were accidental discoveries.
2. The first “prescriptions” were written in the year 3000 BC by the Babylonians. The Chinese have the first recorded volume of plant remedies in the year 2700 BC.
3. Pharmacology was probably viewed as magic and superstition during the Dark Ages. There is very little recorded data from the Dark Ages.
4. Pharmacology first began to be practiced as a science in the 17th century, and the first text with the word *pharmacology* was published in 1693.
5. During the 19th century, chemists were able to make remarkable progress in separating specific substances and the first active agents such as morphine, colchicines, curare, cocaine, and other early drugs were discovered from their natural plant products.
6. The 20th century saw great progress and development of new drugs. We are now able to synthesize drugs from “scratch” in the laboratory.
7. A drug is any substance that is taken to prevent, cure, or reduce symptoms of a medical condition.
8. The word *pharmacology* came from the Greek *pharmakon,* which means “medicine” or “drugs,” and *logos,* which means “study.”
9. The subject of pharmacology is expansive and involves understanding what a drug is given for, how it is administered, where it travels in the body, the actual response it produces, and how it is eliminated.
10. Pharmacotherapy or pharmacotherapeutics is the application of drugs for the purpose of disease prevention and treatment.
11. Over 11,000 brand, generic, and combination agents are available, each with its own application, interactions, side effects, and actions.
12. Many drugs have more than one use. They may be prescribed for more than one disease and many produce multiple effects in the body.
13. Client factors that can cause drugs to elicit a different response are age, gender, race, body mass, health status, and genetics.
14. Staying current and up to date with new drugs is critical for the client and health care provider. Proper application of a drug can improve quality of life, whereas an improperly applied drug can cause disability or even death.
15. Many people believe that there are perfect drugs and that the perfect drug should and can always be selected for the client.
16. The perfect or ideal drug is effective, can be given at low doses, works quickly, has no adverse effects, can be taken conveniently, can be taken infrequently, is inexpensive, is quickly eliminated from the body, and does not interact with other medications or food.
17. There is no such thing as a perfect drug. Drugs that are used most often are ones that are close to the perfect drug profile. Drugs that have a profile that strays furthest from the perfect drug profile are used infrequently.
18. Conditions for which drugs are approved are called *indications*. All prescription drugs have at least one indication and some have multiple indications.
19. Some drugs are used for conditions for which they do not have an approved indication; this is called an *unlabeled* or *off-label use*.
20. Drugs are categorized in two ways: a therapeutic classification and a pharmacologic classification.
21. The therapeutic classification is how the drug is used in treating a specific disease.
22. The pharmacologic classification is the mechanism of drug action or how the drug produces its effects in the body.
23. Drugs may also have multiple therapeutic and pharmacologic classifications that are dependent on the clinical use of the drug.
24. The prototype drug is usually the first and best understood drug in its class, but sometimes the prototype may be a new or clinically more useful drug.
25. By learning about the prototype drug, nurses can understand the depth, actions, and adverse effects of other drugs in the same class.
26. Drugs are identified by multiple names, which can be confusing to both the client and health care provider.
27. Chemical names are assigned by using standard nomenclature established by the International Union of Pure and Applied Chemistry (IUPAC). Each drug has only one chemical name. Drugs can be named and classified by a portion of their chemical structure, known as the chemical group name.
28. Generic names are assigned by Health Canada. Generic names are usually less complicated and are easier to remember than chemical names. Each drug has only one generic name.
29. Trade names are also called *proprietary*, *product*, or *brand names*. The trade name is assigned by the pharmaceutical company and is usually short and easy to remember.
30. Health Canada grants pharmaceutical companies exclusive rights for naming and marketing a drug for a fixed number of years after the new drug application is approved, allowing the company to recoup the cost of research and development.
31. When this exclusivity expires, competing companies may sell a generic equivalent drug. They may give it a different trade name, which the Health Canada must approve.
32. Combination drugs are drugs with more than one active generic ingredient.
33. Because of the potential confusion with trade names, it is important for the nurse to identify drugs by their generic names.
34. Pharmaceutical companies often lobby aggressively against laws that might restrict the routine use of certain brand-name drugs. They claim that there is a difference between a trade-name drug and its generic equivalent and that switching to a generic may be harmful to the client.
35. Consumer advocates argue that generic substitutions should always be permitted because they provide cost savings to the client.
36. Bioavailability is defined by the Federal Food, Drug, and Cosmetic Act as the rate and extent to which the active ingredient is absorbed from the drug product and then becomes available at the site of the drug action to produce the desired effects.
37. Bioavailability may be affected by formulation, inert ingredients, and tablet compression. All of these factors can affect the absorption and/or distribution of the drug.
38. Bioavailability is measured by the time it takes for the drug to exert its effect; it is also known as onset time. Bioavailability may differ between trade and generic drugs.
39. Internet sites may allow clients to purchase drugs at substantial savings. However, the danger of doing so is that the drugs may be sold from other countries and these countries may not have the same quality control standards as the United States. These drugs may be harmful or not effective. The nurse must help clients understand the differences and the potential dangers.