International Journal of Trend in Scientific Research and Development, Volume 1(2), ISSN: 2456-6470
www.ijtsrd.com

The Nursing Pharmacology: An Introduction to Drugs

Evelyn M. Balanquit, MAN
Faculty, College of Nursing and Allied Health Science,
University of Eastern Philippines, Catarman, Northern Samar

ABSTRACT
The human body works through a complicated series of chemical reactions and processes. Pharmacology is the study of the biological effects of chemicals. Drugs are chemicals that are introduced into the body to cause some sort of change. When drugs are administered, the body begins a sequence of processes designed to handle the new chemicals. These processes, which involve breaking down and eliminating the drugs, in turn affect the body's complex series of chemical reactions. In clinical practice, health care providers focus on how chemicals act on people. Nurses deal with pharmacotherapeutics, or clinical pharmacology, the branch of pharmacology that uses drugs to treat, prevent, and diagnose disease. Clinical pharmacology addresses two key concerns: the drug's effects on the body and the body's response to the drug. For many reasons, understanding how drugs act on the body to cause changes and applying that knowledge in the clinical setting are important aspects of nursing practice. For instance, patients today often follow complicated drug regimens and receive potentially toxic drugs. Many patients also need to manage their care at home. A drug can have many effects, and the nurse must know which ones may occur when a particular drug is administered. Some drug effects are therapeutic, or helpful, but others are undesirable or potentially dangerous. These negative effects are called adverse effects. The nurse is in a unique position regarding drug therapy because nursing responsibilities include the following: • Administering drugs

- Assessing drug effects
- Intervening to make the drug regimen more tolerable
- Providing patient teaching about drugs and the drug regimen
- Monitoring the overall patient care plan to prevent medication errors

Knowing how drugs work makes these tasks easier to handle, thus enhancing the effectiveness of drug therapy. This text is designed to provide the pharmacological basis for understanding drug therapy. The physiology of a body system and the related actions of many drugs on that system are presented in a way that allows clear understanding of how drugs work and what to anticipate when giving a particular type of drug.

INTRODUCTION
A drug is a chemical that interacts with proteins in the body to affect a physiological function. This is the general idea behind all medicine. Once these chemicals are absorbed into the systemic circulation they bind with certain proteins and this changes the functioning of the cell slightly. Drugs are substances that change a person's mental or physical state. They can affect the way your brain works, how you feel and behave, your understanding and your senses. This makes them unpredictable and dangerous, especially for young people. The effects of drugs are different for each person and drug.

Objectives

This paper aims to achieve the following:

1. Define the word pharmacology.
2. Outline the steps involved in developing and approving a new drug in the United States.
3. Describe the federal controls on drugs that have abuse potential.
4. Differentiate between generic and brand name drugs and over-the-counter and prescription drugs.
5. Explain the benefits and risks associated with the use of over-the-counter drugs.

Glossary of Key Terms
Adverse effects: drug effects that are not the desired therapeutic effects; may be unpleasant or even dangerous

Brand name: name given to a drug by the pharmaceutical company that developed it; also called a trade name chemical name: name that reflects the chemical structure of a drug

Drugs: chemicals that are introduced into the body to bring about some sort of change

Food and Drug Administration (FDA): federal agency responsible for the regulation and enforcement of drug evaluation and distribution policies

Generic drugs: drugs sold by their generic name; not brand (or trade) name products

Generic name: the original designation that a drug is given when the drug company that developed it applies for the approval process

Genetic engineering: process of altering DNA, usually of bacteria, to produce a chemical to be used as a drug

Orphan drugs: drugs that have been discovered but would not be profitable for a drug company to develop; usually drugs that would treat only a small number of people; these orphans can be adopted by drug companies to develop

Over-the-counter (OTC) drugs: drugs that are available without a prescription for self-treatment of a variety of complaints; deemed to be safe when used as directed

Pharmacology: the study of the biological effects of chemicals

Pharmacotherapeutics: clinical pharmacology—the branch of pharmacology that deals with drugs; chemicals that are used in medicine for the treatment, prevention, and diagnosis of disease in humans

Phase I study: a pilot study of a potential drug done with a small number of selected, healthy human volunteers

Phase II study: a clinical study of a proposed drug by selected physicians using actual patients who have the disorder the drug is designed to treat; patients must provide informed consent

Phase III study: use of a proposed drug on a wide scale in the clinical setting with patients who have the disease the drug is thought to treat

Phase IV study: continual evaluation of a drug after it has been released for marketing

Preclinical trials: initial trial of a chemical thought to have therapeutic potential; uses laboratory animals, not human subjects

Teratogenic: having adverse effects on the fetus.

Sources of Drugs

Drugs are available from varied sources, both natural and synthetic.

Natural sources include plants, animals, and inorganic compounds.

Natural Sources

Chemicals that might prove useful as drugs can come from many natural sources, such as plants, animals, or inorganic compounds. To become a drug, a chemical must have a demonstrated therapeutic value or efficacy without severe toxicity or damaging properties.

Plants

Plants and plant parts have been used as medicines since prehistoric times. Even today, plants are an important source of chemicals that are developed into drugs. For example, digitalis products used to treat cardiac disorders and various opiates used for sedation are still derived from plants. Drugs also may be processed using a synthetic version of the active chemical found in a plant. An example of this type of drug is dronabinol (Marinol), which contains the active ingredient delta-9-tetrahydrocannabinol found in marijuana. This drug helps to prevent nausea and vomiting in cancer patients but does not have all of the adverse effects that occur when the marijuana leaf is smoked. Marijuana leaf is a controlled substance with high abuse potential and has no legal or accepted medical use. The synthetic version of the active ingredient allows for an accepted form to achieve the desired therapeutic effect in cancer patients. Ingestion of a plant-derived food can sometimes lead to a drug effect. For instance, the body converts natural licorice to a false aldosterone—a hormone found in the body—resulting in fluid retention and hypokalemia or low serum potassium levels if large amounts of licorice are eaten. However, people seldom think of licorice as a drug. Finally, plants have become the main component of the growing alternative therapy movement.

Animal Products

Animal products are used to replace human chemicals that fail to be produced because of disease or genetic problems. Until recently, insulin for treating diabetes was obtained exclusively from the pancreas of cows

and pigs. Now genetic engineering—the process of altering DNA—permits scientists to produce human insulin by altering Escherichia coli bacteria, making insulin a better product without some of the impurities that come with animal products. Thyroid drugs and growth hormone preparations also may be obtained from animal thyroid and hypothalamic tissues. Many of these preparations are now created synthetically, however, and the synthetic preparations are considered to be purer and safer than preparations derived from animals. Inorganic Compounds Salts of various chemical elements can have therapeutic effects in the human body. Aluminum, fluoride, iron, and even gold are used to treat various conditions. The effects of these elements usually were discovered accidentally when a cause–effect relationship was observed. Today, many drugs are developed synthetically after chemicals in plants, animals, or the environment have been tested and found to have therapeutic activity. Scientists use genetic engineering to alter bacteria to produce chemicals that are therapeutic and effective. Other technical advances allow scientists to alter a chemical with proven therapeutic effectiveness to make it better. Sometimes, a small change in a chemical's structure can make that chemical more useful as a drug—more potent, more stable, and less toxic. These technological advances have led to the development of groups of similar drugs, all of which are derived from an original prototype, but each of which has slightly different properties, making a particular drug more desirable in a specific situation. Throughout this book, the icon will be used to designate those drugs of a class that are considered the prototype of the class, the original drug in the class, or the drug that has emerged as the most effective. For example, the cephalosporins are a large group of antibiotics derived from the same chemical structure. Alterations in the chemical rings or attachments to that structure make it possible for some of these drugs to be absorbed orally, whereas others must be given parenterally. Some of these drugs cause severe toxic effects (e.g., renal toxicity), but others do not.

DRUG EVALUATION

After a chemical that might have therapeutic value is identified, it must undergo a series of scientific tests to evaluate its actual therapeutic and toxic effects. This process is tightly controlled by the U.S. Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services that regulates the development and sale of drugs. FDA-regulated tests are designed to ensure the safety and reliability of any drug approved in this country. For every 100,000 chemicals that are identified as being potential drugs, only about fi ve end up being marketed. Before receiving final FDA approval to be marketed to the public, drugs must pass through several stages of development. These include preclinical trials and phase I, II, and III studies.

Preclinical Trials

In preclinical trials, chemicals that may have therapeutic value are tested on laboratory animals for two main purposes:

(1) to determine whether they have the presumed effects in living tissue and

(2) to evaluate any adverse effects.

Animal testing is important because unique biological living organisms, so computer-generated models alone are often inadequate. At the end of the preclinical trials, some chemicals are discarded for the following reasons:

- The chemical lacks therapeutic activity when used with living animals.
- The chemical is too toxic to living animals to be worth the risk of developing into a drug.
- The chemical is highly teratogenic (causing adverse effects to the fetus).
- The safety margins are so small that the chemical would not be useful in the clinical setting. Some chemicals, however, are found to have therapeutic effects and reasonable safety margins. This means that the chemicals are therapeutic at doses that are reasonably different from doses that cause toxic effects. Such chemicals will pass the preclinical trials and advance to phase I studies.

Phase I Studies

A phase I study uses human volunteers to test the drugs. These studies are more tightly controlled than preclinical trials and are performed by specially trained clinical investigators. The volunteers are fully informed of possible risks and may be paid for their participation. Usually, the volunteers are healthy, young men. Women are not good candidates for phase I studies because the chemicals may exert unknown and harmful effects on a woman's ova, and too much risk is involved in taking a drug that might destroy or alter the ova. Women do not make new ova after birth. Men produce sperm daily, so there is less potential for complete destruction or alteration of the

sperm. Women who elect to participate in phase 1 studies have to be informed of the potential risk and must sign a consent outlining the possible effects. Some chemicals are therapeutic in other animals but have no effects in humans. Investigators in phase I studies scrutinize the drugs being tested for effects in humans. They also look for adverse effects and toxicity. At the end of phase I studies, many chemicals are dropped from the process for the following reasons:

- They lack therapeutic effect in humans.
- They cause unacceptable adverse effects.
- They are highly teratogenic.
- They are too toxic.

Phase II Studies

A phase II study allows clinical investigators to try out the drug in patients who have the disease that the drug is designed to treat. Patients are told about the possible benefits of the drug and are invited to participate in the study. Those who consent to participate are fully informed about possible risks and are monitored very closely, often at no charge to them, to evaluate the drug's effects. Usually, phase II studies are performed at various sites across the country—in hospitals, clinics, and doctors' offices—and are monitored by representatives of the pharmaceutical company studying the drug. At the end of phase II studies, a drug may be removed from further investigation for the following reasons:

- It is less effective than anticipated.
- It is too toxic when used with patients.
- It produces unacceptable adverse effects.
- It has a low benefi t-to-risk ratio, meaning that the therapeutic benefi t it provides does not outweigh the risk of potential adverse effects that it causes.
- It is no more effective than other drugs already on the market, making the cost of continued research and production less attractive to the drug company. A drug that continues to show promise as a therapeutic agent receives additional scrutiny in phase III studies.

Phase III Studies

A phase III study involves use of the drug in a vast clinical market. Prescribers are informed of all the known reactions to the drug and precautions required for its safe use. Prescribers observe patients very closely, monitoring them for any adverse effects. Often, prescribers ask patients to keep journals and record any symptoms they experience. Prescribers then evaluate the reported effects to determine whether they are caused by the disease or by the drug. This information is collected by the drug company that is developing the drug and is shared with the FDA. When a drug is used widely, totally unexpected responses may occur. A drug that produces unacceptable adverse effects or unforeseen reactions is usually removed from further study by the drug company. In some cases, the FDA may have to request that a drug be removed from the market.

Food and Drug Administration Approval

Drugs that finish phase III studies are evaluated by the FDA, which relies on committees of experts familiar with the specialty area in which the drugs will be used. Only those drugs that receive FDA committee approval may be marketed. An approved drug is given a brand name (trade name) by the pharmaceutical company that developed it. The generic name of a drug is the original designation that the drug was given when the drug company applied for the approval process. Chemical names are names that reflect the chemical structure of a drug. Some drugs are known by all three names. It can be confusing to study drugs when so many different names are used for the same compound.

Phase IV Studies

After a drug is approved for marketing, it enters a phase of continual evaluation, or phase IV study. Prescribers are obligated to report to the FDA any untoward or unexpected adverse effects associated with drugs they are using, and the FDA continually evaluates this information. Some drugs cause unexpected effects that are not seen until wide distribution occurs. Sometimes, those effects are therapeutic. For example, patients taking the antiparkinsonism drug amantadine (Symmetrel) were found to have fewer cases of influenza than other patients, leading to the discovery that amantadine is an effective antiviral agent.

LEGAL REGULATION OF DRUGS

The FDA regulates the development and sale of drugs. Local laws further regulate the distribution and administration of drugs. In most cases, the strictest law is the one that prevails. Nurses should become familiar with the rules and regulations in the area in which they practice. These regulations can vary from state to state, and even within a state. Over the years, the FDA has become more powerful, usually in response to a drug disaster affecting many people. In the 1930s, the drug "elixir of sulfanilamide" was

distributed in a vehicle of ethylene glycol that had never been tested in humans. It turned out that ethylene glycol is toxic to humans, and hundreds of people died and many others became very ill. This led to the Federal Food, Drug and Cosmetic Act of 1938, which gave the FDA power to enforce standards for testing drug toxicity and monitoring labeling. In the 1960s, the drug thalidomide (Thalomid) was used as a sleeping aid by pregnant women, resulting in the birth of many babies with limb deformities. The public outcry resulted in the Kefauver-Harris Act of 1962, which gave the FDA regulatory control over the testing medications. Each prescriber has a DEA number, which allows the DEA to monitor prescription patterns and possible abuse. A nurse should be familiar with not only the DEA guidelines for controlled substances but also the local policies and procedures, which might be even more rigorous.

Generic Drugs

When a drug receives approval for marketing from the FDA, the drug formula is given a time-limited patent, in much the same way as an invention is patented. The length of time for which the patent is good depends on the type of chemical involved. When the patent runs out on a brand-name drug, the drug can be produced by other manufacturers. Generic drugs are chemicals that are produced by companies involved solely in the manufacturing of drugs. Because they do not have the research, the advertising, or, sometimes, the quality control departments that the pharmaceutical companies developing the drugs have, they can produce the generic drugs more cheaply. In the past, some quality-control problems were found with generic products. For example, the binders used in a generic drug might not be the same as those used in the brand-name product. As a result, the way the body breaks down and uses the generic drug may differ from that of the brand-name product. In that case, the bioavailability of the drug is different from that of the brand-name product.

Orphan Drugs

Orphan drugs are drugs that have been discovered but are not financially viable and therefore have not been "adopted" by any drug company. Orphan drugs may be useful in treating a rare disease, or they may have potentially dangerous adverse effects. Orphan drugs are often abandoned after preclinical trials or phase I studies. The Orphan Drug Act of 1983 provided tremendous financial incentives to drug companies to adopt these drugs and develop them. These incentives help the drug company put the drug through the rest of the testing process, even though the market for the drug in the long run may be very small (as in the case of a drug to treat a rare neurological disease that affects only a small number of people).

Over-the-Counter Drugs

Over-the-counter (OTC) drugs are products that are available without prescription for self-treatment of a variety of complaints. Some of these agents were approved as prescription drugs but later were found to be very safe and useful for patients without the need of a prescription. Some were not rigorously screened and tested by the current drug evaluation protocols because they were developed and marketed before the current laws were put into effect. Many of these drugs were "grandfathered" into use because they had been used for so long. The FDA is currently testing the effectiveness of many of these products and, in time, will evaluate all of them. Although OTC drugs have been found to be safe when taken as directed, nurses should consider several problems related to OTC drug use:

- Taking these drugs could mask the signs and symptoms of underlying disease, making diagnosis difficult.
- Taking these drugs with prescription medications could result in drug interactions and interfere with drug therapy.
- Not taking these drugs as directed could result in serious overdoses. Many patients do not consider OTC drugs to be medications and therefore do not report their use. Nurses must always include specific questions about OTC drug use when taking a drug history and should provide information in all drug-teaching protocols about avoiding OTC use while taking prescription drugs or checking with the health care provider first if the patient feels a need for one of these drugs.

SOURCES OF DRUG INFORMATION

The fields of pharmacology and drug therapy change so quickly that it is important to have access to sources of information about drug doses, therapeutic and adverse effects, and nursing-related implications. Textbooks provide valuable background and basic information to help in the understanding of pharmacology, but in clinical practice it is important to have access to up-to-theminute information. Several sources of drug information are readily available. Nurses often need to consult more than one source.

Drug Labels

Drug labels have specific information that identifies a specific drug. For example, a drug label identifies the brand and generic names for the drug, the drug dosage, the expiration date, and special drug warnings. Some labels also indicate the route and dose for administration. Understanding how to read a drug label is essential. Nurses need to become familiar with each aspect of the label.

Package Inserts

All drugs come with a package insert prepared by the manufacturer according to strict FDA regulations. The package insert contains all of the chemical and study information that led to the drug's approval. Package inserts sometimes are difficult to understand and are almost always in very small print, making them difficult to read. The FDA Web site, www.fda.gov, is a good resource for finding the prescribing information or package insert for most drugs.

Reference Books

A wide variety of reference books are available for drug information. The Physician's Desk Reference (PDR) is a compilation of the package insert information from drugs used in this country, along with some drug advertising. Because this information comes directly from the manufacturers and is not refereed in any way, it may not be the best source for obtaining accurate information about a drug. This information is heavily cross-referenced. The book may be difficult to use. Drug Facts and Comparisons provides a wide range of drug information, including comparisons of drug costs, patient information sections, and preparation and administration guidelines. AMA Drug Evaluations contains detailed monographs in an unbiased format and includes many new drugs and drugs still in the research stage. LNDG has drug monographs organized alphabetically and includes nursing implications and patient teaching points. Numerous other drug handbooks are also on the market and readily available for nurses to use.

Journals

Various journals can be used to obtain drug information. For example, the Medical Letter is a monthly review of new drugs, drug classes, and specific treatment protocols. The American Journal of Nursing offers information on new drugs, drug errors, and nursing implications.

Internet Information

Many patients now use the Internet as a source of medical information and advice. Internet sites for obtaining drug information, patient information, or therapeutic information related to specific disease states. Nurses need to become familiar with what is available on the Internet and what patients may be referencing.

SUMMARY

- Drugs are chemicals that are introduced into the body to bring about some sort of change.
- Drugs can come from many sources: plants, animals, inorganic elements, and synthetic preparations.
- The FDA regulates the development and marketing of drugs to ensure safety and efficacy.
- Preclinical trials involve testing of potential drugs on laboratory animals to determine their therapeutic and adverse effects.
- Phase I studies test potential drugs on healthy human subjects.
- Phase II studies test potential drugs on patients who have the disease the drugs are designed to treat.
- Phase III studies test drugs in the clinical setting to determine any unanticipated effects or lack of effectiveness.
- FDA pregnancy categories indicate the potential or actual teratogenic effects of a drug.
- DEA controlled-substance categories indicate the abuse potential and associated regulation of a drug.
- Generic drugs are sold under their generic names, not brand names; they may be cheaper but in some situations are not necessarily as safe as brand-name drugs.
- Orphan drugs are chemicals that have been discovered to have some therapeutic effect but that are not financially advantageous to develop into drugs.
- OTC drugs are available without prescription for the self-treatment of various complaints.
- Information about drugs can be obtained from a variety of sources, including the drug label, reference books, journals, and Internet sites.

REFERENCES:

[1] Aguwa, C. and Akah, P. (2006). How Drugs Act. In C. Aguwa and J. Ogbuokiri (Eds.), A Handbook of Pharmacology for Nursing and Allied Health Professions (pp. 2-7). Nigeria: Africana First Publishers Limited.

[2] Alamgir, A. (2017). Therapeutic Use of Medicinal Plants and Their Extracts: Volume 1. Switzerland: Springer International Publishing AG

[3] Goodman & Gilman's The Pharmacological Basis of Therapeutics, 11th Edition, McGraw-Hill Medical Publishing Division, New York, 2006

[4] Karch, Amy M., Focus on Nursing Pharmacology 8th edition Lippincott Williams and Wilkins, 2019

[5] Kee, Joyce L., Haynes, Evelyn R. and Mc. Cuisition, Linda, E., Pharmacology a Nursing Approach 5th edition Saunders

[6] Lehne, Richard A., Pharmacology for Nursing Care, 8th edition Elsevier (SG) 2015

[7] Drug Handbook 2020

[8] MIMS 2020KS: