Chapter 1 Introduction to Pharmacology: Drug Regulation and Approval

MULTIPLE CHOICE. Choose the one alternative that best completes the statement or answers the question.

- 1) The nurse is teaching a pharmacology class to student nurses. What does the nurse include as key events in the history of pharmacology? Select all that apply.
 - A) Modern pharmacology began in the early 1600s.
 - B) Initial drugs included morphine, cocaine, and penicillin.
 - C) Early researchers used themselves as test subjects.
 - D) Pharmacologists synthesized drugs in the laboratory in the twentieth century.
 - E) The initial intention of pharmacology was to relieve human suffering.

Answer: C, D, E

Explanation:

A) The early roots of pharmacology included the application of products to relieve human suffering, and early researchers used themselves as test subjects. Initial drugs included morphine, colchicines, curare, and cocaine, but not penicillin. Modern pharmacology began in the early 1800s, not the 1600s. By the twentieth century, pharmacologists could synthesize drugs in the laboratory.

Professional Practice

Nursing Practice: Health and Wellness

B) The early roots of pharmacology included the application of products to relieve human suffering, and early researchers used themselves as test subjects. Initial drugs included morphine, colchicines, curare, and cocaine, but not penicillin. Modern pharmacology began in the early 1800s, not the 1600s. By the twentieth century, pharmacologists could synthesize drugs in the laboratory.

Professional Practice

Nursing Practice: Health and Wellness

C) The early roots of pharmacology included the application of products to relieve human suffering, and early researchers used themselves as test subjects. Initial drugs included morphine, colchicines, curare, and cocaine, but not penicillin. Modern pharmacology began in the early 1800s, not the 1600s. By the twentieth century, pharmacologists could synthesize drugs in the laboratory.

Professional Practice

Nursing Practice: Health and Wellness

D) The early roots of pharmacology included the application of products to relieve human suffering, and early researchers used themselves as test subjects. Initial drugs included morphine, colchicines, curare, and cocaine, but not penicillin. Modern pharmacology began in the early 1800s, not the 1600s. By the twentieth century, pharmacologists could synthesize drugs in the laboratory.

Professional Practice

Nursing Practice: Health and Wellness

E) The early roots of pharmacology included the application of products to relieve human suffering, and early researchers used themselves as test subjects. Initial drugs included morphine, colchicines, curare, and cocaine, but not penicillin. Modern pharmacology began in the early 1800s, not the 1600s. By the twentieth century, pharmacologists could synthesize drugs in the laboratory.

Professional Practice

Nursing Practice: Health and Wellness

- 2) The student nurse asks the nursing instructor why he needs to take anatomy and physiology, as well as microbiology, when he only wants to learn about pharmacology. What is the best response by the instructor?
 - A) "You must learn all, since those subjects, as well as pharmacology, are part of the curriculum."
 - B) "Because pharmacology is an outgrowth of those subjects."
 - C) "Because an understanding of those subjects is essential to understanding pharmacology."
 - D) "Knowledge of all those subjects will prepare you to provide the best patient care, including the administration of medications."

Answer: C Explanation:

A) It is essential for the nurse to have a broad knowledge base of many sciences in order to learn pharmacology. The nurse must learn anatomy, physiology, and microbiology to understand pharmacology, not because they are part of the curriculum. Pharmacology is an outgrowth of anatomy, physiology, and microbiology, but this is not the reason for the nurse to learn them. Knowledge of anatomy, physiology, and microbiology prepares the nurse to understand pharmacology, not to provide care such as administration of medications. Professional Practice

Nursing Practice: Health and Wellness

B) It is essential for the nurse to have a broad knowledge base of many sciences in order to learn pharmacology. The nurse must learn anatomy, physiology, and microbiology to understand pharmacology, not because they are part of the curriculum. Pharmacology is an outgrowth of anatomy, physiology, and microbiology, but this is not the reason for the nurse to learn them. Knowledge of anatomy, physiology, and microbiology prepares the nurse to understand pharmacology, not to provide care such as administration of medications. Professional Practice

Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

- 3) The nursing instructor is teaching a pharmacology class to student nurses. The current focus is pharmacology and therapeutics. The nursing instructor determines that learning has occurred when the students make which comments? Select all that apply.
 - A) "Pharmacology is the study of medicines."
 - B) "Therapeutics is the study of the therapeutic use of drugs."
 - C) "Pharmacology is the use of drugs to relieve suffering"
 - D) "Therapeutics is the study of drug interactions."
 - E) "Pharmacology is the study of drugs to prevent disease."

Answer: A, C

Explanation:

A) Pharmacology is the study of medicines and the use of drugs to relieve suffering. Therapeutics is the study of disease prevention and treatment of suffering. Pharmacotherapy is the application of drugs for the purpose of disease prevention.

Evaluation

Nursing Practice: Health and Wellness

Application

B) Pharmacology is the study of medicines and the use of drugs to relieve suffering. Therapeutics is the study of disease prevention and treatment of suffering. Pharmacotherapy is the application of drugs for the purpose of disease prevention.

Evaluation

Nursing Practice: Health and Wellness

Application

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Evaluation

Nursing Practice: Health and Wellness

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Evaluation

Nursing Practice: Health and Wellness

Application

E) Pharmacology is the study of medicines and the use of drugs to relieve suffering. Therapeutics is the study of disease prevention and treatment of suffering. Pharmacotherapy is the application of drugs for the purpose of disease prevention.

Evaluation

Nursing Practice: Health and Wellness

- 4) The nurse administers a vaccine to a child. What is the best understanding of the nurse as it relates to the manufacture of this vaccine?
 - A) The vaccine is most commonly synthesized in a laboratory.
 - B) The vaccine is naturally produced in animal cells or microorganisms.
 - C) The vaccine is produced by natural plant extracts in the laboratory.
 - D) The vaccine is produced by a combination of animal and plant products.

Answer: B

Explanation:

A) Vaccines are naturally produced in animal cells, microorganisms, or by the body itself. Vaccines are not synthesized in a laboratory. Vaccines are not produced by natural plant extracts. Vaccines are not produced by a combination of animal and plant products.

Evaluation

Nursing Practice: Health and Wellness

Application

B) Vaccines are naturally produced in animal cells, microorganisms, or by the body itself. Vaccines are not synthesized in a laboratory. Vaccines are not produced by natural plant extracts. Vaccines are not produced by a combination of animal and plant products. Evaluation

Nursing Practice: Health and Wellness

Application

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Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

Application

- 5) The elderly client has gastrointestinal bleeding. The client says to the nurse "I don't understand this. All I did was take ibuprofen (Advil) for my arthritis." Which plan would be best as it relates to the nurse's education of this client?
 - A) A plan to teach the client to substitute safer drugs like acetaminophen (Tylenol).
 - B) A plan to teach the client to use drugs that bypass the gastrointestinal system, like topical drugs.
 - C) A plan to teach the client to obtain physician approval prior to the use of over-the-counter (OTC) medications.
 - D) A plan to teach the advantages and disadvantages of ibuprofen (Advil).

Answer: D

Explanation:

A) Since elderly clients account for the use of about 40% of all over-the-counter (OTC) medications, it is essential for the nurse to teach clients about the advantages, and the disadvantages, of these medications. Substitution of other drugs may be beneficial, but this cannot be done in all situations. The use of topical drugs may be an option, but the drug a client needs may not be available in this form. It is not a realistic plan to expect clients to contact their physician prior to taking any over-the-counter (OTC) medication.

Planning

Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

Application

- 6) The student nurse is preparing for the first pharmacology exam. In planning for this exam, what is most important for the student nurse to remember about the Health Products and Food Branch (HPFB) of Health Canada? Select all that apply.
 - A) It prevented the sale of drugs that had not been thoroughly tested before marketing.
 - B) The HPFB regulates the use of therapeutic drugs through directorates.
 - C) The HPFB does not regulate natural health products.
 - D) The HPFB is a part of Health Canada.

Answer: A, B, D

Explanation:

A) Until the 19th century there were few standards or guidelines to protect the public from drug misuse. The Health Products and Food Branch (HPFB) of Health Canada is responsible for ensuring that health products and foods approved for sale to Canadians are safe and of high quality. The HPFB regulates the use of therapeutic products through three directorates: Therapeutic Products directorate, Biologics and Genetic Therapies directorate and the Natural Health Products directorate.

Planning

Nursing Practice: Health and Wellness

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Planning

Nursing Practice: Health and Wellness

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Planning

Nursing Practice: Health and Wellness

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Planning

Nursing Practice: Health and Wellness

Application

- 7) The pharmaceutical representative comes to the physician's office and says his pharmaceutical laboratory is marketing a drug that does not need approval by the Food and Drug Act and Regulations. What is the best response by the nurse?
 - A) "Is your pharmaceutical laboratory private? Only public pharmaceutical laboratories need approval from Health Canada."
 - B) "Your pharmaceutical laboratory must be involved in academic research because they are exempt from approval by Health Canada."
 - C) "Is this an over-the-counter (OTC) drug? They do not need approval by Health Canada."
 - D) "Any pharmaceutical laboratory in Canada must have approval from Health Canada before marketing a drug."

Answer: D

Explanation:

A) Any pharmaceutical laboratory, whether private, public, or academic, must obtain approval from Health Canada, before marketing a drug. Private pharmaceutical laboratories must obtain approval from Health Canada before marketing a drug. Pharmaceutical laboratories involved in academic research must obtain approval from Health Canada before marketing a drug. Pharmaceutical laboratories that manufacture over-the-counter (OTC) drugs must obtain approval from the Health Canada before marketing these drugs.

Implementation

Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

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Application

- 8) The nurse is employed by the a company undertaking Clinical trials on a new cardiovascular drug. What is the primary role of the nurse involved in the second stage of drug testing?
 - A) to perform tests on human cells cultured in the laboratory
 - B) to perform tests on the population-at-large
 - C) to perform tests on human clients
 - D) to perform tests on various species of animals

Answer: C

Explanation:

A) Preclinical investigation involves extensive laboratory research. Performing tests on the population-at-large is the stage of post-marketing surveillance. Human client testing, known as clinical trials, which is the second stage of drug testing, takes place in three phases. Stage I - clinical investigators perform tests on 20 - 100 healthy volunteers. Stage II - involves 100 - 3000 selected clients with a particular disease. In stage III - 1000 - 3000 clients with the disease are given the medication. Performing tests on various species of animals is the preclinical investigation stage.

Assessment

Nursing Practice: Health and Wellness

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Assessment

Nursing Practice: Health and Wellness

Application

- 9) The student nurse is taking a pharmacology course and studying the subject of access to new prescription drugs in Canada. Why might access to drugs be delayed and vary among the provinces and territories? Select all that apply.
 - A) Once a drug is approved by Health Canada, there is no delay in getting it to market across Canada.
 - B) Once Health Canada approves a drug it is up to each province and territory to decide which drugs to list on the provincial formulary.
 - C) The Common Drug Review (CDR) Directorate is responsible to ensure availability of new drugs, without delay, to each province and territory.
 - D) The cost of drugs influences access.

Answer: B. D

Explanation:

A) Access to new drugs can be further delayed and may vary among the provinces and territories. Once Health Canada has approved a drug for marketing in Canada, each province and territory must decide which drugs to list on the provincial formulary, and to reimburse under the provincial drug plan. Thus cost of drugs influences access. Public and private insurers have budgets and thus must consider the cost of a drug. A formulary is a list of drugs available for prescribing or dispensing within the province or territory. The Common Drug Review (CDR) Directorate was established in 2002 to coordinate the jurisdictional review of new drugs and provide a list of recommendations.

Evaluation

Nursing Practice: Health and Wellness

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Evaluation

Nursing Practice: Health and Wellness

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Evaluation

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Evaluation

Nursing Practice: Health and Wellness

Application

- 10) The student nurse is studying the difference between the American and Canadian drug approval processes. What is the student nurse's best understanding of the difference between these two governments in the drug approval process?
 - A) America incorporates the private and government sectors; Canada uses only the government sector.
 - B) There is minimal difference; they both rely extensively on government resources.
 - C) America has much stricter guidelines than Canada for approving drugs for the public.
 - D) Canada has much stricter guidelines than America for approving drugs for the public.

Answer: A

Explanation:

A) Health Canada is the federal department that works in partnership with provincial and territorial governments. There are no private companies involved in the process. In America, drug approval involves the government (the Food and Drug Administration (FDA), as well as private drug companies. In America, private as well as government resources are used. America does not have stricter guidelines than Canada for approving drugs for the public. Canada does not have stricter guidelines than America for approving drugs for the public. Evaluation

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Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

Application

- 11) The student nurse has completed an initial pharmacology course and tells the nursing instructor that it was difficult and she is glad it is over. What is the best response by the nursing instructor?
 - A) "It really isn't over; you should take a graduate course next."
 - B) "It may be over, but now you must apply what you have learned to patient care."
 - C) "Learning is always painful, but we must continue anyway."
 - D) "Learning is gradual and continuous; we never completely master all areas of pharmacology."

Answer: D

Explanation:

A) Learning pharmacology is a gradual, continuous process that does not end with graduation. No one can ever completely master every facet of drug action and application, there are new drugs being introduced annually. There is no reason for a student nurse to take a graduate level pharmacology course at this time. It is true that the student must apply what has been learned to patient care, but this response implies that learning is over. Learning is not always painful.

Implementation

Nursing Practice: Health and Wellness

Application

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Implementation

Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

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Implementation

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Application

- 12) The client says to the nurse "My wife and I take the same drug, but we have different side effects "Are we doing something wrong"? What is the best response by the nurse?
 - A) "No. Differences such as your sex, age, weight and metabolism, can result in different side effects."
 - B) "I'm not sure. Maybe the drug is not the same; you should check it."
 - C) "Possibly. This could happen if one uses generic or brand name drugs."
 - D) "I'll have to check. What is the name of the drug you were using?"

Answer: A

Explanation:

A) Drugs may elicit different responses depending on individual client factors such as age, sex, body mass, health status, and genetics. Asking the client to check a medication is fine, but this does not answer the client's question. There are differences between some generic and brand name drugs, but this is not the best answer. The nurse should not have to check the drug; basic knowledge should include knowing that the sex, age, weight and metabolism of clients can result in different side effects.

Implementation

Nursing Practice: Health and Wellness

Application

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Implementation

Nursing Practice: Health and Wellness

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Nursing Practice: Health and Wellness

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Implementation

Nursing Practice: Health and Wellness

Application

- 13) The client comes to the emergency department, diagnosis is a myocardial infarction. The client's husband tells the nurse that his wife has been taking calcium carbonate (Tums) for years for what she thought was indigestion. What is the best response by the nurse?
 - A) "Why did you let her do that? She should have seen a doctor."
 - B) "Well, I am glad she is here, as it certainly wasn't indigestion."
 - C) "Your wife was self-diagnosing, which is generally not a good idea."
 - D) "Your wife should not have self-diagnosed herself. I hope she will be okay."

Answer: C

Explanation:

A) Clients take over-the-counter (OTC) drugs for many reasons. Self-treatment is sometimes ineffective, and the potential for harm may increase if the disease is allowed to progress. Asking the husband why he let his wife take Tums is non-therapeutic and too accusatory; do not ask "why" questions. Telling the husband that "it certainly wasn't indigestion" is judgmental and will alienate the client and husband. Telling the husband "I hope she will be okay" is a very frightening response that implies she might die, and this is non-therapeutic. Implementation

Nursing Practice: Health and Wellness

Application

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Nursing Practice: Health and Wellness

Application

- 14) The nurse is teaching a class for clients about over-the-counter (OTC) medications. The nurse determines that education has been effective when the clients make which statement?
 - A) "We should not take any over-the-counter (OTC) medicine without first calling and checking with the doctor's office."
 - B) "We must read all the directions on the label and seek advice from a healthcare professional, if they are not clear."
 - C) "Medicines that are available over-the-counter (OTC) are really safe, or they would be prescription medicines."
 - D) "We should always ask the pharmacist about how to take the over-the-counter (OTC) medicine."

Answer: B

Explanation:

A) In most cases, clients may treat themselves safely if they carefully follow instructions included with the medication. It is not realistic to expect clients to call the doctor's office before taking any over-the-counter (OTC) medicine. Most OTC medicines have a high margin of safety, but none are considered completely safe. Asking the pharmacist is a good idea, but does not replace reading the label directions. Also, the pharmacist might not always be in the store when the medicine is purchased.

Evaluation

Nursing Practice: Health and Wellness

Application

B) In most cases, clients may treat themselves safely if they carefully follow instructions included with the medication. It is not realistic to expect clients to call the doctor's office before taking any over-the-counter (OTC) medicine. Most OTC medicines have a high margin of safety, but none are considered completely safe. Asking the pharmacist is a good idea, but does not replace reading the label directions. Also, the pharmacist might not always be in the store when the medicine is purchased.

Evaluation

Nursing Practice: Health and Wellness

Application

C) In most cases, clients may treat themselves safely if they carefully follow instructions included with the medication. It is not realistic to expect clients to call the doctor's office before taking any over-the-counter (OTC) medicine. Most OTC medicines have a high margin of safety, but none are considered completely safe. Asking the pharmacist is a good idea, but does not replace reading the label directions. Also, the pharmacist might not always be in the store when the medicine is purchased.

Evaluation

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D) In most cases, clients may treat themselves safely if they carefully follow instructions included with the medication. It is not realistic to expect clients to call the doctor's office before taking any over-the-counter (OTC) medicine. Most OTC medicines have a high margin of safety, but none are considered completely safe. Asking the pharmacist is a good idea, but does not replace reading the label directions. Also, the pharmacist might not always be in the store when the medicine is purchased.

Evaluation

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- 15) The client has skin lesions that have not responded to prescription drugs. He tells the nurse he has heard about some research going on with a new drug and questions why he can't take it. What is the best response by the nurse?
 - A) "Maybe you could contact the drug company about becoming involved in a clinical trial."
 - B) "Your skin lesions really aren't that bad, but maybe the new drug will be available soon."
 - C) "I know it is frustrating, but the Health Canada approval process is in place to ensure that drugs are safe."
 - D) "Health Canada has very strict rules about new drugs; it is important to be patient regarding the review/approval process."

Answer: C

Explanation:

A) Although the public is anxious to receive new drugs, the fundamental priority of health Canada is to ensure that drugs are safe. Also, telling the client that the nurse knows he is frustrated is therapeutic because it communicates that the nurse recognizes what he is feeling. The client could contact the drug company, but this response fosters false hope as he may not be a viable candidate for this drug. Telling the client his skin lesions "aren't that bad" is a non-therapeutic response; the client's perception is his reality. Telling the client to be patient is a condescending response, the client wants relief from the skin condition. Implementation

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