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Chapter 02: Drug Development and Ethical Considerations
McCuistion: Pharmacology: A Patient-Centered Nursing Process Approach, 10th Edition

MULTIPLE CHOICE

1. The nurse is obtaining consent from a subject newly recruited for a clinical drug trial that will last for 6 months. All subjects will be given gift certificates for participating. One subject says, "Well, I guess if the drug doesn't work, I'll just have to put up with the symptoms for 6 months." What will the nurse tell the subject?
   a. "Participation for the duration of the study is required."
   b. "Participation may end at any time without penalty."
   c. "Withdrawal from the study may end at any time, but the gift certificate will not be given."
   d. "You can request placement in the treatment group."

   ANS: B
   All participants have the right to autonomy, which is the right to self-determination. Patients have the right to refuse to participate or to withdraw from a study at any time without penalty. Patients generally are not allowed to choose participation in either the treatment or the control group.

   DIF: Cognitive Level: Understanding (Comprehension)
   TOP: Nursing Process: Nursing Intervention
   MSC: NCLEX: Management of Client Care

2. The nurse is assisting with a clinical drug trial in which the side effects of two effective drugs are being compared. A patient who would benefit from either drug has elected to withdraw from the study, and the nurse assists with the paperwork to facilitate this. This is an example of
   a. autonomy.
   b. beneficence.
   c. justice.
   d. veracity.

   ANS: A
   All participants have the right to autonomy, which is the right to self-determination. Patients have the right to refuse to participate or to withdraw from a study at any time without penalty even if the health care provider disagrees with that choice.

   DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
   MSC: NCLEX: Management of Client Care

3. During a clinical drug trial for a new medication, researchers note a previously unknown serious adverse effect occurring in more than 50% of subjects. The study is discontinued. Which ethical principle is being exercised?
   a. Beneficence
   b. Justice
   c. Respect for persons
   d. Veracity

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ANS: A
Beneficence is the duty to protect subjects from harm. Once a serious adverse effect is noted and it is determined that the benefits do not outweigh the risks of the study, researchers have an ethical obligation to stop the study.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Management of Client Care

4. In a 5-year experimental clinical trial to investigate a new cancer treatment, researchers in the second year note overwhelming improvement in almost all of the subjects in the treatment group. It is decided to stop the trial early and report the findings due to the overwhelmingly beneficial effects. This decision was made based on which ethical principle?
   a. Beneficence
   b. Justice
   c. Respect for persons
   d. Veracity

   ANS: B
   The principle of justice requires that all people be treated fairly. Because the findings were overwhelmingly positive, an ethical decision was made to stop the study early and report findings so that additional people could gain benefit from the treatment.

   DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
   MSC: NCLEX: Management of Client Care

5. The nurse is enrolling subjects for a double-blind experimental study. One patient asks the nurse to explain the role of the experimental group. The nurse will explain that subjects in the experimental group in this type of study:
   a. are selected for participation in that group.
   b. have unique baseline characteristics.
   c. receive a placebo.
   d. receive the experimental treatment being evaluated.

   ANS: D
   In a double-blind experimental study, subjects in the experimental group receive the treatment or drug under study. They are randomly assigned and not selected. They should have similar baseline characteristics to those in the control group. They do not receive a placebo.

   DIF: Cognitive Level: Understanding (Comprehension)
   TOP: Nursing Process: Nursing Intervention: Patient Teaching
   MSC: NCLEX: Management of Client Care

6. The nurse is obtaining signatures on consent forms for participation in a clinical drug trial. One patient says, “I’m not sure I want to do this, but I need the cash.” The nurse will take which action?
   a. Ask the patient to clarify concerns.
   b. Reinforce that cash is given to all subjects equally.
   c. Report this statement to the lead investigator.
   d. Review the elements of the study and obtain consent.

   ANS: C

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If a nurse suspects that a patient is being coerced to participate in the study, the nurse should report this to the principal investigator. When a patient verbalizes participation based on a financial reward, there is a potential element of coercion.

DIF: Cognitive Level: Applying (Application)
TOP: Nursing Process: Nursing Intervention
MSC: NCLEX: Management of Client Care

7. Which is the characteristic of preclinical in vivo testing?
   a. A comparison of experimental and control data in animals
   b. A study conducted in a test tube in a laboratory
   c. A study that determines the effects of the placebo in human participants
   d. A study to assess the seriousness of the disease to be treated

   ANS: A
   Preclinical in vivo testing is performed in animals or other living organisms. In vitro studies occur in test tubes. Safe therapeutic dose studies are part of clinical research. Prior to clinical trials, an assessment is made of the disease and its seriousness.

   DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
   MSC: NCLEX: Management of Client Care

8. Many drugs marketed in the 1980s may not be effective in a majority of the population. The nurse understands that this is because these drugs:
   a. did not pass through the appropriate phases of clinical trials.
   b. did not require human subject protections and are invalid.
   c. were not tested in women, minorities, or children.
   d. were tested on healthy subjects only.

   ANS: C
   Drug research was historically performed only with Caucasian males, causing uncertainty as to the validity of the research results in the broader population.

   DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
   MSC: NCLEX: Management of Client Care

9. The nurse is assisting with data collection in a study of drug effects in as mall group of healthy subjects. The nurse assists with blood and urine collection to determine serum drug levels and the presence of metabolites in urine. Which phase of drug development does this represent?
   a. Phase I
   b. Phase II
   c. Phase III
   d. Phase IV

   ANS: A
   Phase I drug trials are performed to assess safety and to identify the pharmacokinetics, such as metabolism and elimination, of drugs in healthy subjects.

   DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
   MSC: NCLEX: Management of Client Care

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10. The nurse is enrolling subjects for a clinical drug trial in which subjects will be randomly assigned to either a treatment or a placebo group. The pills in both groups will be in identical packaging with identical appearance. The group that receives the intervention is the:
    a. control group.
    b. experimental group.
    c. dependent group.
    d. independent group.

    ANS: B
    The experimental group in a drug trial is the group that receives the drug being tested. The control group may receive no drug, a different drug, a placebo, or the same drug with a different dose, route, or frequency of administration. Dependent and independent are not terms to describe groups in a study; they denote the variables.

    DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
    MSC: NCLEX: Management of Client Care

11. Respect for Persons is a core ethical principle of human subjects research. Which of the following best describes this principle?
    a. Duty to protect research subjects from harm.
    b. Fair selection of research subjects.
    c. Right to self-determination
    d. Patients are independent and capable of making decisions in their own best interests.

    ANS: D
    Respect for persons is based on the notion that patients should be treated as independent persons who are capable of making decisions in their own best interests.

    DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
    MSC: NCLEX: Management of Client Care

12. A clinical drug trial is concluding a study of pharmacokinetics and safety of a drug in healthy individuals. The nurse will assist enrollment of participants into the next phase of the study and will include which subjects?
    a. Healthy subjects
    b. Healthy and ill subjects
    c. Subjects with the disease the drug will treat
    d. Subjects with other diseases

    ANS: C
    After Phase I studies demonstrating drug safety and pharmacokinetics have been completed, the drug is tested on subjects who have the disease the drug will treat.

    DIF: Cognitive Level: Understanding (Comprehension)
    TOP: Nursing Process: Nursing Intervention
    MSC: NCLEX: Management of Client Care

13. Before marketing a new drug that has been approved for use based on clinical effectiveness and safety, the manufacturer wishes to study the potential new uses for the drug. This is an example of which phase of study?
    a. Phase I

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b. Phase II
c. Phase III
d. Phase IV

ANS: D
Phase IV studies are performed, in part, to examine potential new indications for approved drugs.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Management of Client Care

14. Which statement about the safety and efficacy of medications in children is accurate?
a. Children cannot give consent, so clinical drug trials are not performed on children.
b. Children can only be subjects in quasi-experimental clinical studies.
c. Data from adult clinical drug trials should be extrapolated to children.
d. Federal law requires that drugs for children be tested on children.

ANS: D
The U.S. Food and Drug Administration (FDA) Modernization Act of 1997 requires that drugs intended for use in children be tested on children.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Management of Client Care

15. The nurse is preparing to administer a schedule II injectable drug and is drawing up half of the contents of a single-use vial. Which nursing action is correct?
a. Ask another nurse to observe and cosign wasting the remaining drug from the vial.
b. Keep the remaining amount in the patient's drawer to give at the next dose.
c. Record the amount unused in the patient's medication record.
d. Dispose of the vial with the remaining drug into a locked collection box.

ANS: A
Schedule II drugs are controlled substances, and all must be accounted for. When wasting a portion of a drug, another nurse should observe and cosign that a drug was wasted.

DIF: Cognitive Level: Applying (Application)
TOP: Nursing Process: Nursing Intervention
MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

16. A patient is prescribed a medication and asks the nurse if the drug is available in a generic form. The nurse understands that a generic drug name is:
a. a registered trademark.
b. always capitalized.
c. related to the drug's chemical structure.
d. nonproprietary.

ANS: D
The generic name is the official, nonproprietary name for a drug. The brand name is the trademark name and is always capitalized. The chemical name describes the chemical structure of the drug.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A

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MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

17. A patient receives a prescription on which the provider has noted that a generic medication may be given. The patient asks the nurse what this means. What will the nurse tell the patient about generic drugs?
    a. They contain the same inert ingredients as brand-name drugs.
    b. They have chemical structures that are different from proprietary drugs.
    c. They tend to be less expensive than brand-name drugs.
    d. They undergo extensive testing before they are marketed.

    ANS: C
    Generic drugs are approved by the FDA if they are proved to be bioequivalent to the brand-name drug. They tend to be less expensive because manufacturers of these drugs do not have to do the extensive testing required of brand-name drugs before marketing. They are not identical to brand-name drugs and often have different inert ingredients.

    DIF: Cognitive Level: Applying (Application)
    TOP: Nursing Process: Nursing Intervention: Patient Teaching
    MSC: NCLEX: Management of Client Care

18. The nurse reviews information about a drug and notes the initials "United States Pharmacopeia (USP)" after the drug's official name. The nurse understands that this designation indicates the drug:
    a. is a controlled substance.
    b. is approved by the FDA.
    c. is available in generic form.
    d. meets USP quality and safety standards.

    ANS: D
    The "USP" designation is given to drugs that have met high standards for therapeutic use, patient safety, quality, purity, strength, packaging safety, and dosage form by the United States Pharmacopoeia National Formulary. The FDA classifies controlled substances with Roman numerals from I to V. The USP designation does not indicate FDA approval. The USP designation does not indicate generic availability.

    DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
    MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

19. The nurse is preparing to give a medication to a child. The medication is approved for use in children. The child's parent asks whether the drug is safe for children. How will the nurse respond to the parent?
    a. "Drugs approved for use in children are tested on adults and safe doses for children are based on weights compared to adult weights."
    b. "Drugs approved for use in children are deemed safe for children over time when repeated use proves effectiveness and safety."
    c. "Drugs approved for use in children are tested for both efficacy and safety in children in order to be marketed for pediatric use."
    d. "Drugs approved for use in children are tested on children in post-marketing studies and on a limited basis."

    ANS: C

The Pediatric Research Equity Act requires drug manufacturers to test drugs on children.

DIF: Cognitive Level: Applying (Application)
TOP: Nursing Process: Nursing Intervention
MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

20. Which law(s) govern all drug administration by nurses?
    a. Drug Regulation and Reform Act
    b. FDA Amendments Act
    c. Nurse Practice Acts
    d. The Controlled Substances Act

ANS: C
Each state's Nurse Practice Act identifies how nurses administer medications. The other acts govern how drugs are marketed and tested.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

21. A patient is taking methadone as part of a heroin withdrawal program. The nurse understands that, in this instance, methadone is classified as which drug schedule?
    a. C-I
    b. C-II
    c. C-III
    d. C-V

ANS: B
Methadone is a category II drug, with a high potential for drug abuse.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

22. The nurse is preparing to administer a combination drug containing acetaminophen and codeine. The nurse knows that this drug is classified as which drug schedule?
    a. C-II
    b. C-III
    c. C-IV
    d. C-V

ANS: B
Codeine is normally a category II drug, except when it is part of a combination product such as with acetaminophen, making it a category III drug.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

MULTIPLE RESPONSE

1. Which are responsibilities of the FDA? (*Select all that apply.*)
    a. To ensure a drug has accurate labeling.
    b. To ensure a drug is affordable.
    c. To ensure a drug is effective.

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d. To ensure a drug is free from adverse reactions.
e. To ensure a drug is tested for harmful effects.

ANS: A, C, E
The FDA ensures that drugs are labeled correctly, that they are tested and proven effective for the conditions they are marketed to treat, and that they are tested for harmful effects. The FDA does not ensure affordability or freedom from adverse reactions, although these must be noted in drug information materials.

DIF: Cognitive Level: Understanding (Comprehension) TOP: Nursing Process: N/A
MSC: NCLEX: Physiological Integrity: Pharmacological and Parenteral Therapies

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