



Implementation and Management of Clinical Trials

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1. Of the following types of studies, which requires the largest accrual of subjects to receive new drug approval from the U.S. Food and Drug Administration (FDA)?
 - a. Phase I
 - b. Phase II
 - c. Phase III
 - d. Phase IV
2. Most clinical trial participants learn of trials from
 - a. Physicians or nurses.
 - b. Web sites.
 - c. Family members or friends.
 - d. Newspaper articles.
3. About what percentage of adult patients with cancer is aware that clinical trials may be a possible treatment option?
 - a. 15%
 - b. 30%
 - c. 50%
 - d. 75%
4. A patient is eligible to participate in a randomized clinical trial that compares treatment with a standard chemotherapy agent (arm A) to treatment using that same chemotherapy agent in combination with an experimental therapy (arm B). Which of the following elements of the informed decision process should the nurse incorporate when discussing this trial with the patient?
 - a. Informing the patient that this is a research study, providing a description of the treatment regimens of both arms of the study, and discussing potential risks and benefits of both treatments along with alternative treatment options
 - b. Providing a detailed description of the treatment regimen that the patient would be randomized to and discussing potential risks and benefits of this treatment
 - c. Informing the patient that this is a research study and describing the probable outcomes of the two treatment options
 - d. Informing the patient that the physician decides whether the patient participates in the trial and which treatment arm is assigned
5. A patient has signed a consent form to participate in a phase III clinical trial and is randomized to the investigational therapy arm of the trial. As the nurse prepares to administer the investigational therapy, the patient states, "I was hoping I wouldn't get an investigational drug. That scares me. The only reason I agreed to participate in this study is that I did not want to upset my doctor and family. I do not want people experimenting on me." The nurse's most appropriate response would be to
 - a. Reassure the patient and proceed with administering the investigational treatment.
 - b. Proceed with investigational treatment and later inform the physician of the patient's concerns.
 - c. Not administer the investigational therapy and send the patient home with instructions to contact his physician.
 - d. Not administer the investigational therapy and immediately contact the physician to discuss the patient's concerns.
6. Which of the following is the purpose of an institution's clinical trial review process?
 - a. To ensure that the rights and welfare of investigators are protected
 - b. To ensure that the rights and welfare of clinical trial sponsors (funding agencies) are protected
 - c. To ensure that the rights and welfare of humans participating as research subjects in clinical trials are protected
 - d. To approve institutional clinical trial budgets and ensure that the studies are funded sufficiently
7. A patient has expressed interest in clinical trial participation but tells the nurse that he saw a television show about the Tuskegee Syphilis Study in which patients were treated like "guinea pigs." He also expresses concern about expenses related to clinical trial participation and states, "I cannot afford to pay anything that Medicare doesn't cover." What is the nurse's best response to the patient's concerns?
 - a. "Your concerns are well founded. It is best that you do not participate in this clinical trial. Other treatment options that are covered by Medicare can be discussed with your physician."
 - b. "Patients in clinical trials today are treated well, not like guinea pigs. Medicare will not cover any of your medical expenses if you participate in a clinical trial, so that may be a consideration regarding your participation."
 - c. "Regulations have been developed and are followed by people involved in conducting clinical trials to ensure that participants are treated with professionalism and respect and that their rights are protected. Furthermore, Medicare will pay for all routine costs that are part of a clinical trial."
 - d. "It is possible to receive inferior care while in a clinical trial; however, it is possible that the treatment is more effective. Medicare will cover all routine costs associated with clinical trial participation."

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