

## Ethical and Legal Issues in Clinical Practice: Medical Devices Quiz

Directions: Select the Best response for each item.

1. Conformance with \_\_\_\_\_ determines the ethicality and legality of a clinical decision.
  - A. current local practices
  - B. professional standards of care
  - C. economics
  - D. supervisors' instructions
2. Which of the following are legitimate sources for standards of care?
  - A. AARC Clinical Practice Guidelines
  - B. The Joint Commission for Accrediting Healthcare Organizations (JCAHO)
  - C. State professional credentialing boards
  - D. All of the above
3. Most respiratory care devices are classified by the Federal Drug Administration in which category?
  - A. Class I
  - B. Class II
  - C. Class III
  - D. Class IV
4. The Federal Drug Administration would classify a new type of ventilator, that is not equivalent to those currently on the market, in which category?
  - A. Class I
  - B. Class II
  - C. Class III
  - D. Class IV
5. Deaths that occur due to medical devices must be reported to the Federal Drug Administration within what time interval?
  - A. 24 hours
  - B. 10 days
  - C. 30 days
  - D. No report is required
6. Which of the following is an organization that provides means for voluntary reporting of problems with medical devices?
  - A. The Emergency Care Research Institute (ECRI)
  - B. The Commission for Accreditation of Respiratory Care (CoARC)
  - C. The Joint Commission for Accrediting Healthcare Organizations (JCAHO)
  - D. The National Board for Respiratory Care (NBRC)
7. When a medical device functions according to manufacturer's specifications; but, fails under specific clinical circumstances, this is an example of \_\_\_\_\_.
  - A. Product defect
  - B. Device misuse
  - C. Design defect
  - D. All of the above
8. All of the following are elements of negligence guilt, EXCEPT:
  - A. injury to the patient
  - B. duty to care for the patient
  - C. slander
  - D. proximate cause
9. Measuring a patient's oxygen saturation by applying a finger sensor to the ear is an example of:
  - A. device misuse
  - B. product defect
  - C. design defect
  - D. appropriate clinical practice
10. Which of the following are responsibilities of respiratory care managers in promoting device safety?
  - A. Final device adoption decisions
  - B. Directing evaluation trials
  - C. Ensuring staff competency
  - D. All of the above