1st Class

September 9, 2018

I - Legal and Ethical Aspects of Medication Administration

Nurses and Drug research (pp 24-30)

Involvement of nurses in drug research:

Informed consent: Written consent to an individual after he or she has been given a careful explanation of the:

- a. Nature, purpose, procedure, drugs or devices involved
- b. Identification of any experimental procedures
- c. Potential benefits, risks and discomforts to participants
- d. Alternative treatments
- e. Confidentiality of research records
- f. Compensation if injury occurs
- g. Persons to contact about rights
- h. What to do if research results in injury
- i. A statement that research is voluntary and that withdrawal does not incur penalty

Flaws of other client consents:

- a. Incomplete information conveyed
- b. Information not delivered in a non medical language
- c. Presented at a time when the client is sleepy or sedated and not fully cognizant of the ramifications of what is being signed

Obligation of the nurse

- 1. Ensure that flaws don't happen
- 2. It is the researcher who gives the full explanation and answers pertinent questions

Ethics Codes and Acts:

1. Nuremburg Code (1947):

Protects the rights of the human participants in medical research was developed under the aegis of American physicians as a result of the post World War II Nuremberg trials of the Nazi physicians who had conducted experiments on political prisoners without their consent.

This code include the following:

- 1. Truly voluntary consent of the human subject is critical
- 2. The experiment must be proved to be valid or made possible only through the use of human subjects
- 3. The study justifies the results and risks
- 4. Unnecessary suffering, death or disability will be avoided
- 5. The experiment will be conducted in a careful and professional manner by scientifically qualified persons

6. Either the subject or the investigator can terminate the experiment at any point that the experiment is thought to be unendurable or impossible.

2. Declaration of Helsinki (1964):

Refined the rules and regulations of clinical research

3. National Research ACT (1974):

Emphasized protection of human subjects, IRB guidelines, overall good clinical practice in research (Tuskegee Syphilis Study)

4. Belmont Report (1979):

Provided additional guidelines for more inflexible protection of subjects and focused on respect, beneficence and justice as a basis for interdisciplinary research.

Ethical and legal responsibilities of nurses related to research on experimental drug development

- 1. Nurse's action should be based on adequate knowledge and skill and those clients are protected from foreseeable harm.
- 2. Nurse needs to know the recommended dosage range and route of administration, desired therapeutic effects and undesired and toxic effects of the drug under study.
- 3. Throughout the entire investigation, the nurse must strictly adhere to the protocols of the study
- 4. The nurse should record all investigations as precisely as possible because they will have a direct influence on the outcome of the study

Legal Requirements before drug administration

- 1. Medication order must be valid
- 2. The physician /prescriber and the nurse must be licensed. The non-physician prescriber must be prescribing within the regulations of the state.
- 3. The nurse must know the purpose, actions, effects and major adverse effects of the drug, and the teaching required to enable the client or caregiver to self-administer the drug safely and accurately.

Characteristics of a valid order:

- 1. No doubt regarding the medications prescribed, its dosage and route, dosing interval, and the prescriber's name and signature
- 2. The drug must be deemed appropriate for that specific client
- 3. The medication order must be written and ordered in a way that it is correct, complete, legible, and clearly understandable.

Incorrect or inappropriate order:

- 1. A dose too high for a client of a low body weight or impaired renal function.
 - a. It is the nurse or nursing student's absolute right and responsibility to question any proposed action that is potentially harmful to a client
 - b. No one can relieve the nurse of responsibility for the nurse's actions
- 2. A nurse to carry out an order that the nurse knows to be incorrect constitutes Negligence
- 3. Changing an order by modifying any part of it without consultation with the prescriber is similarly **illegal**

Suggested actions medication errors

- 1. Validate the order by consulting with the pharmacist, an authoritative reference source
- 2. If the order is apparently incorrect, objectively report the conflicting facts and discuss it with the prescriber in a factual, non blaming manner
- 3. If the prescriber insists that the medication be administered, Inform the immediate supervisor, and seek consultation
- 4. If the drug is given, the medication record should reflect that it was the prescriber who gave it.

Ethic-legal issues:

- 1. **NEGLIGENCE** administering an unfamiliar drug even though remaining in ignorance of its actions and its intended effects and adverse effects
- 2. **MALPRACTICE** A behavior or procedure that was not of the quality reasonably expected of someone with a nurse's professional education and experience under the particular experience
- 3. **ACCOUNTABILITY** taking the responsibility for and be answerable for the service they provide or make available

Six rights of medication administration

- 1. Right medication (one that was prescribed and one that is not contraindicated)
- 2. Right client (not someone else's medication by mistake, nor the medication of the person of the person in the next bed)
- 3. Right dose as prescribed and appropriate
- 4. Right route, form of the drug and administration technique
- 5. Right time for the dose (usually within 30 minutes of the time indicated and at the beneficial intervals as ordered
- 6. Right documentation

Guidelines for litigation free professional nursing practice and medication administration

- 1. Know the limitation of nursing practice in the community by being aware and abiding by the agency policies, joint medical and nursing practice statements, nursing practice acts and state and federal laws
- 2. Know the limitation of one's own skills, expertise, knowledge and experience, and never exceeding them
- 3. Inform involved personnel and document thoroughly all happenings related to client care, especially those with potential legal implications
- 4. Maintain a professional caring, professional and collaborative relationship with clients and their families

Nurse responsibilities to clients according to Code of Ethics:

- 1. Promote health
- 2. Prevent illness
- 3. Restore health
- 4. Alleviate suffering

Principle of nursing Ethics

- 1. **NONMALFEASANCE** the duty to do no harm
- 2. **BENEFICENCE** the duty to do good
- 3. **AUTONOMY** client empowerment
- 4. **JUSTICE** fair and equal treatment for all
- 5. **FIDELITY** faithfulness to one's obligations
- 6. **INTEGRITY** being true to one's word

Tenets of the codes of practice for nurses

Client and nurses will act in the client's best interest

- 1. Respect the client's values, whether or not the nurse agrees with the client's decision in relation to his or her health care
- 2. Assist the client in the decision making process by ensuring that the client is informed of the risks and benefits of the therapy and can make a knowledgeable decision

Boundaries for safe Practice is provided by:

- 1. Laws
- 2. Acts
- 3. Codes
- 4. Regulations shaping the Pharmacologic Practice

Drug regulation:

Food and drug administrating (USA)

Food and drug regulation (CAN)

Saudi food and drug authority (KSA)