Al-Mustaqbal University College

Pharmacy Ethics 3rd stage

Ethical Principles Part II

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Fidelity

- Loyalty
- The basis of accountability
- Includes the professionals faithfulness or loyalty to agreements & responsibilities accepted as part of the practice of the profession

Confidentiality

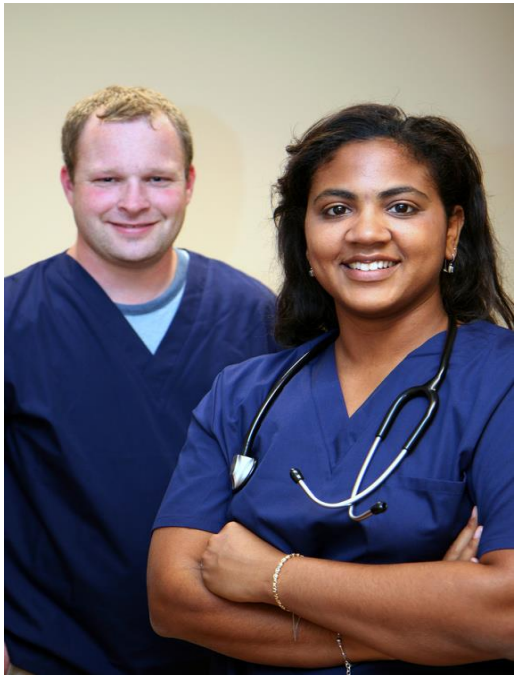
- Anything stated to pharmacists or health-care providers by patients must remain confidential
- Based on trust.
- Maintain the confidentiality of all personal, medical and treatment information.
- Information to be revealed for the benefit of the patient and when ethically and legally required.
- The only times this principle may be violated are:
  - If patients may indicate harm to themselves or others
  - If the patient gives permission for the information to be shared

Veracity

- This principle implies “truthfulness”
- pharmacists need to be truthful to their clients
- Veracity is an important component of building trusting relationships

Accountability

- Individuals need to be responsible for their own actions
- pharmacists are accountable to themselves and to their colleagues



Informed consent

- is the process in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.

- The patient must be competent to make a voluntary decision about whether to undergo the procedure or intervention

What is informed consents..???

- Informed consent is a communication process:

✓ Between the researcher and the participant.

✓ Starts before the research is initiated .

✓ Continues throughout the duration of the study .

✓ Providing all relevant information to the volunteer/ patient

✓ The patient/ volunteer understanding the information provided

✓ A basic right

Historical background of informed consent

- ✓ 1891- Prussian Minister of Interior , tuberculin for the treatment of tuberculosis must not be used against a person's will.
- ✓ 1898- Dr. Albert Neisser was fined by the Royal disciplinary court of Prussia for not seeking patient's consent for his experimental studies of vaccination for Syphilis.
- ✓ 1907- Sir William Osler endorsed the necessity of informed consent in medical research.
- ✓ 1931- Health Department regulations of German Reich stated that both human experimentation and the use of novel treatment required consent in a clear and unbeatable manner.
- ✓ 1945-1966 NIH funded 2000 research projects, none of them use informed consent Thalidomide- Birth defects is found
- ✓ National Research Act (1960-1970) National Commission for protection of research participants in Biomedical and Behavioral Research.
- ✓ 1979,Belmont Report

Belmont Report

- The *Belmont Report* was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles

Elements In Informed Consent Form

1. Protocol number or name of study
2. Purpose of the study.
3. Duration of study and subject involvement
4. A statement that the protocol, and the informed consent were reviewed with the participant, including the risks and benefits of the study.
5. Alternative treatment options discussed.
6. Confidentiality record
7. No of subjects

Elements In Informed Consent Form

8. Compensation for injury
9. Time for questions to be asked and answered.
10. Description of the participant's decision
11. Contact details
12. Use understandable language
13. Copy of consent was given to the participant
14. Sign copy of institute

Informed Consent form

Readability

- Language that is easily understood
- Language must be appropriate to the population being studied
- Language translators should be qualified and authorized
  - **Consider comprehension as well as readability**
  - **Limit medical terminology**

How does informed consent apply to children?

1. Children ***do not*** have the ***decision-making capacity*** to provide informed consent.

2. Since Therefore, ***parents or other surrogate decision-makers*** may give informed permission for diagnosis and treatment of a child, preferably with the assent of the child whenever possible.

Inform consent in pregnant women

practioner should obtain informed consent from ***both*** the pregnant woman and the father

Consent of the father is not necessary if

The purpose of the intervention is to meet the health needs of the mother.

When Patient In Incapable

- Some factors may make a patient incapable of providing competent consent either temporarily or permanently.
- Examples include the following:

1. Mental illness or mental retardation
2. Alcohol or drug intoxication
3. Altered mental status
4. Brain injury
5. Being too young to legally make decisions concerning health care

References:

-Robert J. Pharmaceutical Care Practice: The Clinician's Guide, 2nd Edition.

- Internet search.