Third stage\2nd course
Pharmacy Ethics

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What is clinical research?

It is medical research on human subjects

Improving or validating the effectiveness of methods for preventing injury/ illness.

Investigation of the cause of injury/ illness.

Understanding of clinical conditions.

Improving or validating diagnostic or treatment methods in medicine.

Contents

- Meaning of research and medical researcher
- Research ethics and objective of research ethics
- Ethical principles
- Ethical issues in drug development
- Clinical trails
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Research

 Research refers to “an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge” (1).

Researcher’s primary responsibility is the generation of knowledge, which may or may not contribute to the research subject’s health and wellbeing(2).

Medical researchers study diseases and conditions to improve public health(2).

❖**Good Research Practice (GRP) should ensure (2)**

- ✓ Research is well-planned,
- ✓ Appropriately designed and
- ✓ **Ethically approved**.

Research ethics and objective of research ethics(2)

- **Research ethics** are the set of ethical guidelines that guides us on how scientific research should be conducted and disseminated.

- **Objective of research ethics**

Ethical principles

Basic ethical principles that must be followed in research

- The Belmont Report identified three basic ethical principles that also need to be followed: **respect for persons (autonomy), beneficence and justice** (1,3).

1. Respect for persons (autonomy): This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from all potential research subjects (or their legally authorized representatives).

- Voluntary consent is essential, addresses the importance of treating individuals as autonomous agents and protecting those who have diminished autonomy (for example, prisoners, children, or persons with physical or mental disabilities) (1).

Elements of informed consent must include (1):

1. Inform patients of the procedures, purpose, and risks of the study

2. Present information in a manner that the patient would understand

3. Allow patients to make their own decision without feeling pressured into participating in the study

4. Should also include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and notes to the possibility that the FDA may inspect the records

Cont.

2. Beneficence: This principle requires that researchers maximize benefits and minimize harms or risks associated with research.

Research-related risks must be reasonable in light of expected benefits. (1)

A duty of care to prevent harm is generally made by

(a) Ensuring the adequacy of pretrial safety data and

(b) By appropriate supervision and monitoring during and if necessary following the trial.

3. Justice: This principle focuses on the need to ensure fairness and equity in the selection of research participants and in the distribution of the costs and benefits of research (1)

Examples on justice

- Justice For example, instead of making seriously ill patients come to the hospital for tests needed in a protocol, justice may require sending a nurse to their home, making it as easy as possible on them to participate(4).

- Just because the patients are available doesn't necessarily make them the ideal targets for a research study. Example doing Research on expensive anti HIV drug in poor country with many AIDS patients like South Africa is not justifiable since these patients will not be able to pay for expensive drugs (4).
- Human experimentation is justified only if the results benefit society, and the experimentation is carried out in accordance with basic principles that satisfy moral, ethical, and legal concepts. (1)

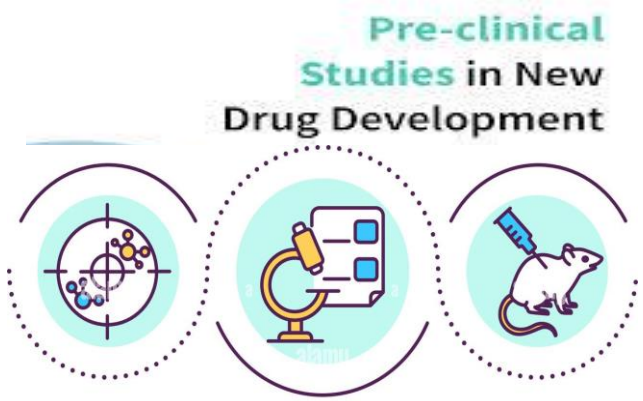
Ethical issues in drug development

- Research about drug development is one of the main activities of pharmaceutical companies.

- Usually those diseases suffered by people in **developed nations** will be more attractive for the pharmaceutical companies. For example, not much research is being carried out by pharmaceutical companies on drugs for AIDS as the vast majority of AIDS sufferers are from the third world such as those from the African continent. Ethically this is not right (3).

- In 1962, Congress amended the act to require drug manufacturers to prove to the FDA that drugs they wished to market were effective as well as safe(1).

Formal validation involves testing both in animals and in humans



 In the first instance, there is a requirement for testing in animals for evidence of potential activity, mode of action, metabolic route and toxicity. **(Preclinical studies).**

 Once empirical safety and activity are confirmed, subsequent testing in human beings is undertaken to determine basic pharmacokinetics, pharmacodynamics, and to evaluate effectiveness and freedom from adverse effects.

Clinical trials and research is needed for drug approval, there are 4 Phases for drug approval

- **Phase I:** small-scale study in healthy volunteers (about 20–80) to assess pharmacokinetics, safe or tolerable dosage and route of administration(5)

- **Phase II:** clinical studies in patients (100–300) suffering from relevant disease to provide evidence of effective dosage, and safety (5).

- **Phase III:** clinical studies in patients (1000–3000) to establish formal safety, effectiveness and comparability with other drugs (5).

- **Phase IV**: postmarketing studies in patients to identify low-level adverse effects (unlimited or > 3000) (5).

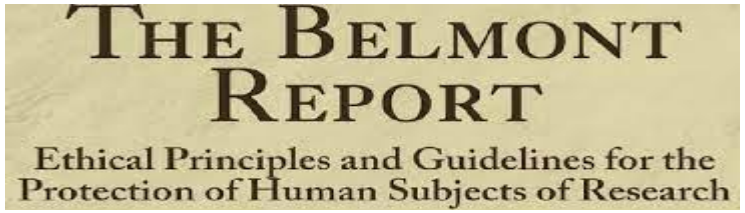
Clinical trails

1-All clinical trials need to be approved by the national institutional ethics committee (IEC) in the country where they are carried out (3).

2-Clinical trials will be conducted only if they can be scientifically and medically justified and potential benefits outweigh potential risks (3).

3-Clinical trials should always be conducted according to **global human rights declarations** such as

- the Declaration of Helsinki,
- the Nuremberg code,
- the Belmont report and
- The International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice (3).



Approval of Research proposals

Research is described in a formal proposal or protocol which indicates an objective and the procedure to reach that objective (1).

- **The ethics committee of clinical research** is the institutional entity at the local institution that is responsible for protecting the rights of human, this committee is composed of members and at least **one clinical pharmacist** must be a member of the ethics committee (4).
- The ethics committee may approve the project as presented, require changes before it can start, or refuse approval altogether.

Cont.

 Commonly ethics committees have reservations on the use of a placebo as it is seems to be very unethical to give subjects with the disease condition a placebo.

 So placebo will **only** be used if ethically acceptable for example if the new treatment is given in addition to the existing treatment,

 a placebo can be used to mask whether the participant is receiving the new treatment and the existing treatment, or just the existing treatment

References

1. DAVID A.GETTMAN. Pharmacoethics. 2003

2. Medical Ethics manual, 3rd edition, 2015

3. M. I. Noordin (2012). Ethics in Pharmaceutical Issues, Contemporary Issues in Bioethics, Dr. Peter A. Clark (Ed.), ISBN: 978-953-51-0169-7.

4. Robert M. Veatch. Case studies in Pharmacy ethics, 2nd edition. 2008.

5. Joy Wingfield, etal. Pharmacy Ethics and Decision Making. 2007

Any question?

Thank you

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1. Basic ethical principles are……., ……., ……..
2. Good research practice should ensure ……., ……., ……..
3. Global human right declaration such as ……., ……., ……..
4. Clinical trial phases include 4 phases:
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