Professionalism

Ethics of Medical Research

(11)

Objectives:

1)Identify the main principles of medical research ethics.

2)Discuss the balance of research and clinical care.

3)Describe requirements of ethics review committees, including definition of informed consent.

4)Identify the key international and national references for the rules and regulations of medical research

Done by:
Reema Al-Rasheed
Sarah Al-Mubrik

Correction File

This work covers:
our slides + 433/432 teamwork

Main Functions of Medical Research:

- **Monitoring** and evaluation of drugs / treatments being used.
- **Understanding** human physiology .
- **Causes** of diseases and the best ways to **prevent** or cure them.
- The development of **new treatments**, especially drugs, medical devices and surgical interventions.
- Factors in human health, including patterns of disease **(epidemiology)**
- The organization, funding and delivery of healthcare **(health systems research)**
- Social and cultural aspects of health (**medical sociology and anthropology**)

Why do practicing physicians need a good understanding of medical research methods?

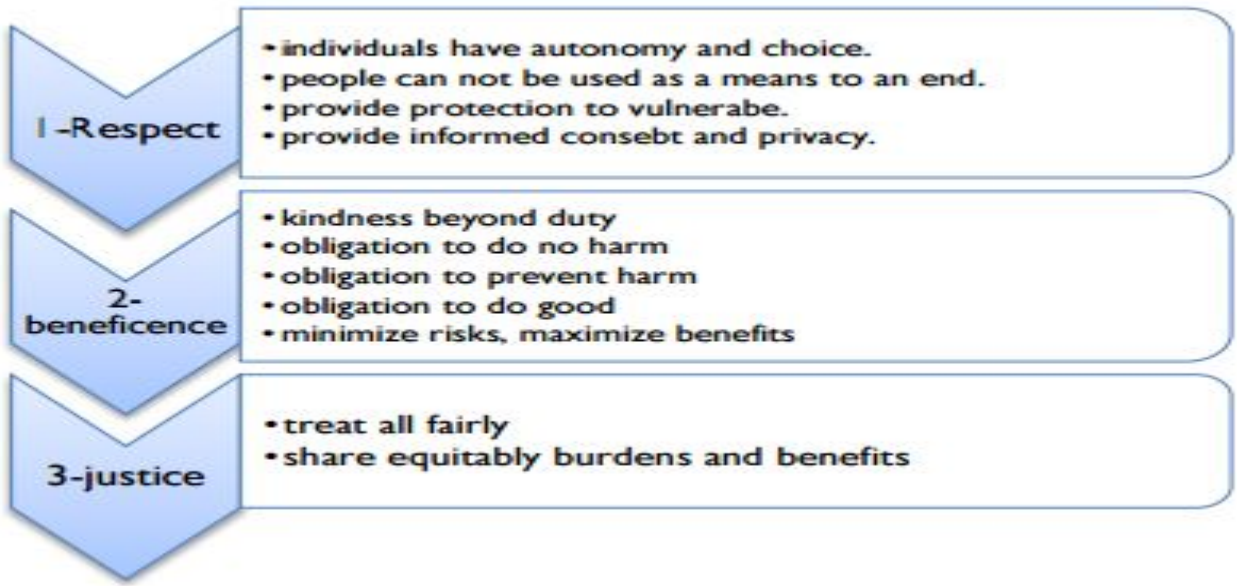
- All physicians **make use** of the results of medical research in their clinical practice.
- To **maintain** their competence, physicians must keep up with the current research , they must know how to interpret the results of research and apply them to their patients.

(2) Potential problems for practicing physicians:

- The physician's primary responsibility is the health and well being of the patient, whereas the researcher's primary responsibility is the **generation of knowledge,** which may or may not contribute to the research subject's health and wellbeing.
- Conflict of interest when the physician is influenced by **financial gains** from research or results of the research.

Principles of Research with Human Subjects:

1. Respect for Persons	1- معاملة الإنسان كشخصية مستقلة له رأيه الحر دون إكراه.
2. Beneficence	2- الإحسان ومنع الإساءة كما يجب أن الا يصيب الإنسان الضرر نتيجة للبحث.
3. Justice	3- العدل في العبء و الفائدة المرجوة من البحث.



Main ethical research requirements:

• Voluntary consent	• For good of society
• Animal experiments 1st;	• Avoid unnecessary suffering
• Do not conduct if death & debility likely human experiments 2nd	• Risk commensurate with benefits
• Protect subjects against harm	• Conducted only by qualified persons
• Subjects should be at liberty to discontinue	• Terminate if becomes apparent that death or debility will occur.

Elements Should Be Included In An Informed Consent:

- **Purpose** of the research
- **Procedures** involved in the research
- **Alternatives** available should a subject decide not to participate in the research
- All foreseeable **risks** and discomforts to the subject. *Note that these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- **Benefits** of the research to society and possibly to the individual human subject
- **Length** of time the subject is expected to participate
- **Payment** for participation (if applicable)
- **Person to contact** for answers to questions or in the event of a researchrelated injury or emergency
- Statement that participation is **voluntary** and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' right to **confidentiality** and right to **withdraw** from the study at any time without any consequences.

If You Have Any Questions Or Comments Please Inform Us:
professionalism434@gmail.com

Declaration of Helsinki (DoH)

Definition: a concise summary of research ethics. Other, much more detailed, documents have been produced in recent years on research ethics in general. Issued by: World Medical Association

Important points of :

1. Ethics Review Committee Approval: Medical research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed.

2. Scientific Merit: Medical research involving human subjects must be justifiable on scientific grounds

3. Qualified researchers : Medical research involving human subjects must be conducted by qualified researchers.

4. Social Value: Medical research project should that it contributes to the wellbeing of society in general.

5. Risks and Benefits: It is also necessary for the researcher to demonstrate that the risks to the research subjects are not unreasonable or disproportionate to the expected benefits of the research, which may not even go to the research subjects.

6. Informed Consent: The first principle of the Nuremberg Code reads as follows: "The voluntary consent of the human subject is absolutely essential.

7. Confidentiality Research subjects have a right to privacy with regard to their personal health information.

8. Conflict of Roles The physician's role in the physician-patient relationship is over the researcher's role, even if the physician and the researcher are the same person.

9. Honest Reporting of Results Research results be reported accurately, but unfortunately there have been numerous recent accounts of dishonest practices in the publication of research results.

10. Whistle-blowing:In order to prevent unethical research from occurring, or to expose it after the fact, anyone who has knowledge of such behavior has an obligation to disclose this information to the appropriate authorities.

11. Justice:
Equitable selection of participants, i.e., avoiding participant populations that may be unfairly coerced into participating, such as prisoners and institutionalized children. The principle of justice also requires equality in distribution of benefits and burdens among the population group(s) likely to benefit from the research.

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Informed consent

Definitions:

Voluntary agreement given by a person or a patients' responsible proxy (e.g.a parent) for participation in a study, etc., after being informed of the purpose, methods, procedures, benefits, and risks. The essential criteria of informed consent are that the subject has both knowledge and comprehension, that consent is freely given without duress or undue influence, and that the right of withdrawal at any time is clearly communicated to the patient. Other aspects of informed consent in the context of epidemiologic and biomedical research, and criteria to be met in obtaining it, are specified in International Guidelines for Ethical Review of Epidemiologic Studies and International Ethical Guidelines for Biomedical Research Involving Human Subjects.

The National Committee of Medical & Bioethics consists of the following sub-committees:

- **The legal sub-committee.**
- **The human research sub-committee.**
- **The flora & animal sub-committee.**
- **The education & media sub-committee.**

What the research ethics committees look for in a research proposal?

- **Scientific design and conduct of the study**
- **Risks and potential benefits**
- **Selection of study population and recruitment of**
- **research participants**
- **Inducements, financial benefits, and financial costs**
- **Protection of research participants' privacy and confidentiality**
- **Informed consent process**
- **Community considerations**

MCQ's

1) You have conducted a research and collected a sample before 6 years, the samples are still good to use. You wanted to do another research using the same sample, what should you do?

A. Asking for the owners for their premission again
B. Ask for Declaration of Helsinki
C. Throw the sample in the garbage
D. Use the sample, you already took theier premession once!

2) You are doing a research to compare between Ciproflaxacin and ceftrixime in treating UTI, the function of your research is?

A. medical sociology and anthropology
B. Monitoring and evaluation of drugs.
C. Understanding human physiology .
D. Causes of diseases and the best ways to prevent or cure them.

1-A 2-B

Quiz

- What are the main functions of medical research?
- Why do practicing physicians need a good understanding of medical research methods? What are the potential problems for practicing physicians?
- What are the principles of research with human subjects stated in Belmont report? What are the important points mentioned in Helsinki (DoH)?
- What elements should be included in an informed consent?