MAL-PRACTICES AND MISCONDUCT IN HEALTH RESEARCH

TANZAMBO WORKSHOP ON HEALTH RESEARCHG ETICS

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Introduction

- Research refers to activities designated to develop or contribute to generalisable knowledge
- Biomedical Research includes:

  - Medical/Health care- operational, intervention, diagnosis
  - Biochemical or pathological process
  - Clinical/Experimental trials-drugs, vaccines, diagnostic equipment, delivery system
  - Health systems research
  - Community studies - Behavioural /Psychological, DSS

Different types of health research involve different **designs** and procedures/protocals.

- Also differ in possible levels of abuse
- Randomization –problem esp. in clinical trials

- **Malpractice** results from -non-adherence to standard procedures or protocals
- **Misconduct** refers to deviation from expected ethics of the medical profession

Throughout the history of human research there have been various violations of research standards and abuses of human (and animal) study subjects/participants

Boundaries between Practice and Research

- **Practice-**interventions designed to enhance well-being of individual patient and have reasonable expectation of success
  - Medical or behavioural practice aims at providing diagnosis, preventive treatment/therapy to particular individual

- **Research-**described in formal protocol, contributes to generalisable knowledge for health care/improvement in the community/society

DOCUMENTED UNETHICAL RESEARCH

1. **Syphilis serum therapy experiments** on prostitutes- by Albert Neisser, the discoverer of gonococcus

- 1898 published clinical trials on serum therapy in patients with syphilis
  - ➢ injected cell free serum from patients with syphilis into patients who were admitted for other medical conditions
  - ➢ most of the patients were prostitutes, who were neither informed about the expt. nor asked for their consent
  - ➢ when some of them contacted syphilis, Neisser concluded that the "vaccination" did not work
  - ➢ Publication of the work triggered public debate which led to his trial-fined for lack of consent

DOCUMENTED UNETHICAL RESEARCH……..

- Led to **Prussian directive (1900)** to all hospital medical directors
- Emphasized need for **"informed consent"** (vague) after "proper explanation of possible negative consequences"
- Required cases to be "documented in the medical history"

2. Horrible crimes committed on war prisoners in Nazi Germany during World War II (ref.RMJ,313,1996)

- Hazardous expts mostly resulting into death or disfigurement-transplantation, poisons, drugs, freezing, sterilization, etc.
- 23 physicians prosecuted -7 received death sentence, 9 life imprisonment
  - ➢ led to **The Nuremberg Code(1947)** on Permissible Medical Experiments (10 principles)

3.Tuskegee syphilis clinical trials (1932-1972)

- ➢ In Alabama by USA Public Health Service aimed - at justifying treatment programs for Blacks

- Involved untreated syphilis in Black males, despite known treatment
- Led to enactment of National Research Act which created the National Commission for the Protection of Human subjects of biomedical and behavioural research in 1974.
- Emphasised **‘informed consent’** and IRB review
- Led to **The Belmont Report** (1979) which laid down:

- Boundaries between Practice and Research
- Basic Ethical Principles : respect for persons, beneficence, justice

4. Bezwoda dubious breast cancer research reports

- 1995 falsely reported high efficacy and safety of high-dose chemotherapy and bone-marrow transplants for advanced breast cancer
- About 15% of 30,000 American women who the expensive treatment died
- Was just fired from his university position

5. **Unethical plague research in Lushoto??**

Note: Clinical research most vulnerable

Regulatory measures:

After The Nuremberg Code, a series of guidelines for physicians in biomedical research involving human subjects were formulated

- Most widely adopted is the **Declaration of Helsinki** with subsequent amendments

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects.

Adopted by the 18th WMA General Assembly

Helsinki, Finland, June 1964

and amended by the

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

- For strict regulations in research involving human subjects and in particular **clinical research**, more stringent regulations and guidelines have been formulated.
- These include:
  - Good Clinical Practice (**GCP)**
  - Good Clinical Laboratory Practice **(CLP)**
  - Good Laboratory Practice (**GLP)**
  - Pharmaceutical industries are further governed by **ICH** (International Conference for Registration of pharmaceuticals)

ETHICAL PRINCIPLES

- Three approaches to **ethical thinking** about research
  - **goal-based approach-** aims at producing greatest possible balance of value over disvalue
  - **duty-based approach**-based on researcher's own moral principles
  - **rights based**-rights of individual assumed to be all important

Basic Ethical Principles

- Refers to those general judgements that serve as basic justification for the many particular ethical prescriptions and evaluations of human actions.

- **The Belmont Report (1979) -d**escribes three:
  - Respect for Persons
  - Beneficence
  - Justice

Ethical Principles

- Always binding unless they are in conflict with other principles –in which case it is necessary to justify why one principle has been chosen over the other
- Four Principles now in place:
  - **Autonomy**
  - **Non-Maleficence**
  - **Beneficence**
  - **Justice**

1. AUTONOMY

"We ought to respect the right to self-determination"

- Need to recognise someone's capacities and perspectives and their right to make choices about whether in any research project or not they take part
- Need also to treat that person so as to allow them to act in an autonomous way
- Autonomy protected by ensuring that any consent to participate is **informed or "real"**

- Sets rules for **“informed consent”**

- Elements;
  - mental capacity
  - ability to understand
  - voluntariness-freedom to participate/withdraw
  - freedom from influence/control

Factors contributing to non-compliance to ‘Autonomy’

- Language
- Social practices and culture
- Incentives/inducement/compensation
- Family/community influence
- Protection of persons with diminished/minimal autonomy
- Lack of respect for study participants and community

2. NON-MELEFICENCE

‘we ought not to inflict evil or pain’

- We may not inflict harm on or expose people to unnecessary risk as a result of our research project
- In medicine, this principle obliges doctors to provide treatment and keep people alive, the **‘Hippocratic maxim’-** ”do not harm”
- This obligation to treat may be over-ridden when (a) treatment is pointless with no prospect of improvement (b) side effects of treatment compromise quality of life

3. BENEFICENCE

‘we ought to further other’s legitimate interests’

- Refers to acts of kindness or charity-beyond strict obligation-human participants are treated in an ethical manner—
  - not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being
- Maximize possible benefits and minimize possible harms

4. JUSTICE

“we ought to ensure fair entitlement to resources”

- Also ‘**treat people fairly**’
- **Fair distribution of burdens and accrued resources (benefits)**
  - Ensuring availability of research benefits/outcome to participating communities
- Involves: fair selection of study subjects – avoid systematic selection of subjects on the basis of easy availability

Non-compliance

- Due to conducive environment for exploitation esp. by Multilateral research
  - Poverty
  - limited heath care infrastructure
  - Poor understanding
  - cultural and traditional practices
  - poor regulatory infrastructure

ETHICAL RULES

- Just like the Principles, they are not absolute-may over-ride one another: justify
- Like the ethical principles on which the rules are based, there are four:
  - veracity
  - privacy
  - confidentiality
  - fidelity

VERACITY

- All subjects in any research project should always be told the truth

- There is no justification for lying-not the same as ‘non-disclosure of information’- where can invalidate the research

PRIVACY

- Defined in term of having control over the extent, timing and circumstances of sharing oneself (physically, behaviourally or intellectually) with others
- When participants/subjects provide information about themselves they do so in a relationship of trust-and expect that it will be shared only as necessary.
- The participant “trust” must be respected by research team and make sure that they do not betray the confidence placed in them.

CONFIDENTIALITY

- Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged (without permission) to others in ways that are inconsistent with the understanding of the original disclosure.
- This can be ensured by:
  - proper coding, limit access to data, proper storage and management of data, etc.

FIDELITY

- Keeping our promises and avoiding negligence with information (as above).

- Includes normal operations and reporting

END