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Vulnerability, vulnerable groups

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- Provisions of 2008 Declaration of Helsinki related with the vulnerable
- Concepts of vulnerability in the DoH
- Definitions and inclusions
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Provision 9

- Provision 9:
Some research populations are particularly vulnerable and need *special protection*. These include who cannot give or refuse *consent* themselves and those who may be vulnerable to *coercion or undue influence*.

- Consent-based
- Need of special protection
- Under undue influence, including coercion

Provision 17

- Provision 17:

Medical research involving a *disadvantaged or vulnerable* population or community is only justified if the research is responsive to the health needs and priorities of this population or community, and if there is a reasonable likelihood that this population or community stands to *benefit* from the result of the research.

- Disadvantaged – par with the vulnerable
- Unfair benefits as result of research interaction
- Exploitation potential

Provision 21

- Provision 21:

Medical research may only be conducted if *the importance of the objective* outweighs the inherent risks and burdens to the research subjects.

- Research value outweighs inherent risks of research subjects.
- No primacy of research subjects' own interests
- Probably vulnerable by potential of exploitation

Provisions 26

- Provision 26:

... if the potential subject is in a *dependent relationship with the physician*, or may consent *under duress*. ...

- Relationship factors as undue influence

Provisions 31

- Provision 31:

The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic *value* and if the physician has *good reason to believe* that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

- Dependent on the physician's belief and judgment on research value.

Provisions 27,28,29,35

- Provision 27: incompetent subjects, informed consent
 - Provision 28: incompetent subjects, assent
 - Provision 29: unconscious patients, emergency patients...
 - Provision 35: unproven intervention
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- Incapacity for consent
 - Without established evidence of safety and effectiveness
 - Critical and desperate state with increased likelihood of taking risks

Vulnerable subjects in the DoH

- Who needs special protection
- Incapacity for consent
- Under undue influence, under duress
- Disadvantaged
- When research objectives are important
- Who is in a dependent relationship with the physician
- Whose condition renders them unable to consent
- Who is in critical state or is desperate in need of even an unproven intervention

Factors associated with vulnerability in DoH

- Individual factors – mental & physical condition
 - Factors inherent to research design – e.g. research value, level of evidence
 - Research context – e.g. situation, information disparity
 - Undue influence – e.g. relational factors, coercion, hierarchy..
 - Broader context – e.g. disadvantaged, SES, minorities, service access...
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- Inclusive enough to comprise almost all research subjects

Major theories & problems

- Consent-based
- Harm-based
- As a claim to special protection
- Based on legal principle, governed by regulatory agencies
- Validity problem – Human behavior is affected by a wide range of influences
 - Harms come in degrees.
 - No same danger, no similar risks
 - No definite line between vulnerable and non-vulnerable
 - Wide grey area, needs clarification

Problems of categorization into groups

- No specification about how each group differs in regard to vulnerability
- No difference in the source and type of vulnerability between individuals included in a group
- No differential criteria for special protection according to each characteristics of research, research environment
- Conflict with the principle of respect
- Potential of labeling

Piling up problems

- Which characteristics should be seen as rendering a subject vulnerable?
 - Which circumstances should be seen as rendering subjects vulnerable?
 - How different is each subject's vulnerability?
 - Which type and what level of vulnerability is?
 - What sort of protections properly address these various vulnerability?
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- How to incorporate the principle of respect and to move beyond the dichotomy of 'active researcher' and 'passive research subject'?

Difficulties in defining the concepts

- The concepts of vulnerability inevitably depend on non-scientific and individual subjective considerations.
- Research by its nature implies that there always will be considerable uncertainty regarding outcomes. Assessing risks and benefits of forefront research becomes more and more problematic with the development of science and technology.

The principle of protection in the DoH

- Underlying principles throughout DoH's past revisions remain same.
- The principle of protection: 'Research subjects are inherently vulnerable and researchers have potential to exploit subjects in the interests of science.'
- By broad inclusion, the principle reflects the public needs of our times, rather than losing its force.
- *"Perhaps what is surprising is not the realization that all research subjects could be considered vulnerable, but rather that it has taken so long to recognize this to be the case."*
F Grinnell(2004) Am J Bioethics. 4,3;72-
- What matters is not the principle, but how to interpret it and to realize it.

The character of the Declaration of Helsinki

- The DoH is the product of HISTORY.
- The DoH is a document of ETHICAL PRINCIPLES.
- The DoH has certain size.
- The DoH has been referred to and regarded as a last resort at all times.

- Generally, principle guides reasoning, and is interpreted into regulations and guidelines in countries.

- Regulations and guidelines change with times, while principles endure.
- Regulation is based upon applicability and depend on the infrastructure of a society. Each regulation would differ according to healthcare system, law system, social/cultural structure of countries.
- Quite volume of books would be required to specify all the regulations and guidelines

Principles vs. regulations/guidelines

- What matters is not the principle of protection, but
- How to set regulations balancing between ‘the principle of protection’ and ‘the principle of respect’
- How to apply regulations appropriately
- How to make it sure that the regulations are being followed
- Who shares the duty to avoid the potential harms and wrongs?
- Who has the responsibility for the harms and wrongs?
- How to adjust them properly with times and to go with the change of society and technology development

Comments

- Principle of protection as a broad definition of vulnerability and a broad inclusion
- With a considerable scope for interpretation and specification
- It would be sufficient, if the principle accompanies
 - Requirement of balanced view with the principle of respect
 - Clear description about responsibility of oversight
 - Clear positioning of accountability of harms and wrongs