



Vulnerable populations

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Outline of presentation

- What is vulnerability
 - Factors that may cause vulnerability
 - Vulnerable groups/populations
 - Research involving vulnerable groups
 - What do some international guidelines say?
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- **Interactive presentation**

Vulnerability

- What does vulnerability mean?
- What factors do you think can render people vulnerable?

Vulnerability

- Vulnerability means inability or limited ability to protect ones own interests
- Vulnerable people are “individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate” ICH E6

Vulnerable people

- People who are liable to be:
 - exploited
 - harmed
 - deceived
 - cheated
 - wronged
 - unfairly treated
 - etc

What do some international guidelines say?

- “Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. ...they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (Paragraph 1, Commentary on CIOMS 13)

Factors that may cause

vulnerability

- Poverty: at various levels
- Lack of/low levels of education
- High burden of diseases in context of poverty
- Highly authoritarian system or environment
- Mental illness
- Being minors
- Pregnancy
- Lack of/limited freedom to exercise the right to self-determination
- Legal framework or cultural/religious

What are some vulnerable groups that you know?

Vulnerable groups/populations

- Refugees
- Prisoners
- Desperately poor people/patients
- Patients in emergency situations
- Children
- Pregnant women
- Institutionalized people (e.g. nursing homes)
- People at the bottom of a hierarchical structure
 - Army, Police force, school, college
- Homeless people

Should vulnerable people be involved in research at all?

Declaration of Helsinki 2008

- “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 results of the research.” point # 17

Research with vulnerable people

- Would it be justifiable to recruit vulnerable people in the following types of research:
 - Epidemiological studies
 - Biomedical research on samples from vulnerable people
 - Social studies
 - Behavioral studies
 - Survey focusing on some health related issue
 - Phases I, II, or III clinical trial of a vaccine
 - Phases I, II, or III clinical trial of a drug?

THANK YOU