“Critical review of informed consent and autonomy in the context of biomedical research in developing countries”

Rethinking Informed Consent: The limits of autonomy

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Overview

- Informed consent: elements and definition
- Difficulties with IC globally identified
- Difficulties with IC in developing countries
- The need to rethink IC, autonomy and vulnerability

INFORMED CONSENT

"Informed consent is a decision to participate in research, taken by a ***competent*** individual who has received the ***necessary information***; who has ***adequately understood*** the information; and who, after considering the information, has arrived at a decision without having been subjected to ***coercion, undue influence or inducement, or intimidation.***"

CIOMS, 2002

Difficulties globally identified

- No unique definition of competence
- Informed consent as a researcher protection vs. participants protection and empowerment
- Confusion between procedure and compliance with adequate content
- Document vs. process (ethical quality of the relationship)
- Low rates of understanding and remembering the contents of IC by participants
- Language too technical and (Intl funded research), too much information, others, too scare.

Difficulties globally identified

- Psychological vulnerability due to Illness, fear, hope that:
  - Interfere with understanding and remembering
  - Influence re-interpretation or misunderstanding
  - Use of psychological mechanisms: such as denial related to risks
  - Therapeutic misconception

Difficulties globally identified

- Asymmetry in the researcher-participant encounter (participants lack experience of being heard).

Although global, more relevant in developing countries.

Difficulties in Developing Countries Context

- **Governments:**
  - **Restricted capacity to deliver health services:**
    - **Low coverage**
    - **Imbalanced budgets**
    - **Poor management**
    - **Scare human and material resources**
  - **Pressures on them by pharmaceutical and commercial organizations.**
- **Disparities in health care in a globilized world.**
- **Disparities in legal, health-care, ethical infrastructure within the diverse regions**

Difficulties in Developing Countries Context

- Population participating in most clinical and health research:
  - restricted access to health (research means access to treatment and health care!!!)
  - Hierarchical systems in health systems reproduce social models (physician-patient; women) (idiosyncratic) (active defense of civil and patient rights) Lack of satisfaction for basic needs in general: education (incredibly high rates of analphabetism), hunger; hence disempowered, discriminated and stigmatized; not full exercise of rights.
  - Conflict of interest and dependence: regular physician and researcher at the same time (people feel care is charity and fear to loose it; confidence in their physician)

Difficulties in Developing Countries Context

- **Different meanings of signature:**

(particularly rural areas)

  - **Offense: word and trust is still the most important value**
  - **Fear to loose rights or properties, or information being used against them (past experiences)**
  - **Signature socially associated with irreversible commitment, then how to withdraw any time?**
- **Need to develop and accept alternative ways of documenting the process: trained witnesses, tape recording, etc.**

Difficulties in Developing Countries

- Most people do not read and write:
- Reading scores are not enough even if people read due to cultural and idiosyncratic reasons
- The social meaning of some medical practices and the cultural dimension of technical terms or procedures are ingored
- Literal language translations do not capture social and cultural meanings
- Many indigenous population with very different understanding of life, health, etc

RETHINKING AUTONOMY

Informed consent aims to protect autonomy:

Autonomy:

- Decision made with non external influence vs. moral agents making autonomous decisions
- Thus: create conditions to enable them to do so.

RETHINKING AUTONOMY

Autonomy:

Ability to make decisions on a concrete situation, but how to ignore circumstances in which such decisions are made?

In developing countries (Nal & Intl. funded research):

living conditions of participants are very likely to be considered as undue inducement (defined as: "giving too much") , where to draw the line when nothing is available?

RETHINKING VULNERABILITY

Vulnerability:

Psychosocial-economical & cultural conditions of participants in developing countries

Poverty: deprivation has an impact on agency and freedom

RETHINKING INFORMED CONSENT

CULTURALLY SENSITIVE

Differences in culture often mean differences in access to power:

thus danger of ignoring or perpetuating inequalities

RETHINKING INFORMED CONSENT

How informed, understood and free from coercion and undue inducement?

- Strategies to enhance & measure information and comprehension: cartoons, multimedia, reading scores, comprehension questions;
- personal relationship and extra time (more effective)..but still

RETHINKING INFORMED CONSENT

- Need to measure “voluntariness” and freedom
- Need to develop and to implement educational with long and short term interventions prior to the informed consent process
- More research on participants needs in terms of necessary, adequate and sufficient information