GENEVA / YAOUNDE ETHICS WEEK

AUTONOMY AND INFORMED CONSENT

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AUTONOMY ACROSS CULTURES

- Autonomy literally implies self-regulation and self-legislation (*auto + nomos*); hence self rule
- It implies uniqueness and individuality (not individualism)
- It implies both the freedom, personal dignity and agency of the individual
- It also implies the (moral) equality of all human beings
- “It is a most terrible thing for the actions of an individual to be subject to the will of another”
- “Over herself, over her own body and mind, the individual is sovereign and has absolute right”
- Autonomy plus freedom equals responsibility
- Autonomy is one of the foundational pillars of morality across cultures
AUTONOMY VARIOUSLY EXPRESSED

- *Wan dze wan; wir dze wir:* (a child/human person is a child/human person)
- Do unto others as you would have them do unto you (*The Golden Rule*)
- Always treat human beings as ends in themselves and never merely as means to any other end
- A human society is possible only where people act according to the principle of sympathetic impartiality
AUTONOMY AS THE PRIMUM INTER PARES OF CARDINAL PRINCIPLES

• In Western ‘principlism’ autonomy is given pride of place, in line with the cultural thrust of individualism, both right (liberty) and left (egalitarianism)

• It is argued that the other so-called cardinal principles of bioethics – beneficence, non-maleficence and justice – all require respect for the autonomy of others

• Autonomy translates directly into the requirement of informed consent in research involving human subjects
INFORMED CONSENT OR INFORMED DECISION-MAKING
WHAT IS INFORMED CONSENT OR DECISION-MAKING?

- Informed consent is a *process* which begins before and continues throughout the course of a research project.
- In the process information is given, explanations made, questions are asked and answered, discussion engaged and decisions made etc.
- Informed decision-making includes informed *dissent* (potential participant’s right to decline participation).
Elements of informed consent

➢ *Preconditions*
  • Competence (to understand and freely and autonomously to decide)
  • Voluntary willingness (in deciding)

➢ *Information elements*
  • Disclosure by investigator (of all relevant information)
  • Understanding by potential participant

➢ *Consent elements*
  • Questions by potential participant
  • Decision by potential participant
The consent form

• It documents the consent process.
• It cannot substitute for the consent process.
• Its purpose is *not* to provide legal protection for the researcher(s).
• Its purpose is to familiarize participants with the purpose and details of the research and to keep a verifiable/checkable record.
Why is informed consent important?

- Nuremberg Code and Helsinki Declaration
- *Principle of respect for persons and their autonomy*
  - Treat people as ends-in-themselves, not merely as a means or instrument to other ends
  - Distinction between research and therapy

- *Past abuses by unscrupulous researchers*
  - Atrocities committed by physician-researchers in Nazi-Germany
  - Contemporaneous abuses in the USA
  - Other examples (South Africa, Nigeria, Cameroon)?
Nuremberg Code (Article 1) / UNAIDS-WHO Guidelines 2000 (Guideline Point 12)

- “The voluntary consent of the human subject is absolutely essential”

- Such consent must be “based on complete, accurate, and appropriately conveyed and understood information…”
Some Controversial Issues and Unanswered Questions

- Must participants always sign consent forms? (What has a signature got to do with it?)
  - What of illiterate participants?
  - What of participants unwilling to sign out of fear, mistrust or suspicion?
  - Possible risks of signing the forms (identification of participant in sensitive research such as HIV/AIDS, drugs, prostitution, rare genetic conditions)
  - What of “community consent”?  
  - What if genuine informed consent cannot be obtained?
IN THEORY

- Informed Consent (IC) is the centre piece of the ethics of medical research involving humans
- IC is the main focus of the Nuremberg code (1947)
- Prominent preoccupation of other regulatory documents: the Helsinki Declaration, Belmont Report, CIOMS Guidelines etc.
- IC is directly deducible from the cardinal ethical principle of respect for persons in their autonomy
- IC is, from the point of view of ordinary commonsense, the minimal-lest of conditions for experimentation on a human being
- IC must be sufficiently informed, freely given and genuinely voluntary
IN PRACTICE

- Fulfilling the requirement of IC in actual concrete situations faces hurdles and challenges
- These differ from place to place and from time to time
- Ethical principles are universal but not applied *in abstracto*
- *In concreto*, they must necessarily adapt to different particular circumstances, context, perspective, procedures, ways of doing; while remaining universally valid
- Genuine IC can only be appraised in practice *in situ* and not theoretically *in vaccuo*

- However, as an ethical imperative, hurdles and challenges notwithstanding, IC is not optional; it implies an ‘ought’ and ought implies ‘can’
WHY MAY GENUINE IC BE UNOBTAINABLE?

- The therapeutic misconception
- The therapeutic illusion
- Inducement (due or undue)
- Ignorance
- Misunderstanding
- Subjects are minors or incompetent adults
WHAT OUGHT TO BE DONE IN THAT SITUATION?

• What situation?
• Any situation in which genuine IC is unobtainable
ARE THEY CHILDREN?  
(Helsinki 25, CIOMS 14)

• Research must not be such as can be carried out on adults
• Purpose of research is to obtain knowledge relevant to the health needs of children
• A competent parent or legal representative of each child has given permission
• The assent of each child has been obtained to the extent of its capabilities
• Child’s refusal to participate or continue in the research will be respected
ARE THEY INCOMPETENT ADULTS? (Helsinki 24, CIOMS 15)

• Should not be research that could be carried out on competent adults
• Purpose is to obtain knowledge relevant to the particular health needs of similarly impaired persons
• Consent must be obtained to the extent possible and refusal respected
• Permission must be obtained from competent/responsible family member or legal representative
ARE THEY FULLY COMPETENT ADULTS?

• “Many believe that informed consent makes research ethical. However, informed consent is neither necessary nor sufficient for ethical clinical research” (Ezekiel J. Emanuel, David Wendler, Christine Grady, JAMA 2000:283: 2701-2711)

• The first part of the above statement is probably true
• The second part is not only false but liable to be highly misleading; it may leave the impression that IC could be dispensed with under certain circumstances
• The correct statement would be to say that IC is a necessary condition which is not sufficient for ethical clinical research
• As a necessary condition, the impediments/hurdles to IC should and can be overcome before research is engaged
OF NECESSARY AND SUFFICIENT CONDITIONS

• A necessary condition may or may not be sufficient, but there is no going around it; it is ‘incontournable’

• Femaleness, for example, is a necessary but not sufficient condition for motherhood, since not all females are mothers; but no one could become a mother unless she were a female

• Whereas fertilization is both a necessary and sufficient condition for pregnancy

• There may be situations where IC is given but where, nevertheless, it would be unethical to carry out research; e.g. where study design is faulty and would lead to no discovery or where risks by far outweigh possible benefits
CONCLUSION

• To believe that IC makes clinical research ethical is to mistake a *necessary* for a *sufficient* condition
• To wonder how research may be carried out when genuine IC cannot be obtained is like wondering how a non-female could become a mother
• IC is certainly not sufficient but it is necessary; only in league with other conditions can it become sufficient for ethical research
• Non-obtention of IC clearly seems to mark out a no-go area of ethical research on human beings
• Can you imagine a situation or circumstances under which research would be ethically permissible in the absence of informed consent?