‘Bioethical Reflexivity’ and Requirements of Valid Consent: Conceptual Tools

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Background (BMC Medica Ethics Call)

"…. Obtaining valid consent to research participation is a benchmark of ethical practice and there is extensive national, regional, and international guidance on how this is to be achieved. *Despite this guidance, valid consent to research participation in low income settings is far more than a primarily practical challenge: it remains highly complex normatively*".

"... It is envisaged that the thematic series will contribute to the *development of conceptual frameworks for categorising the complex issues and the reasons they arise*, the development of policies and processes to support valid consent, and to identify priorities for future conceptual analysis and empirical research".

Introduction

- In the conduct of health-related research, valid consent by participants is one of the key hallmarks for ethical conduct of research.

- The persisting controversy, especially in LMICs, is how to obtain and ascertain valid consent (Ballard et. al. 2004; Mangset et al 2008. Kang et. al. 2010; Helchen 2012; Bromwich & Mullum 2017; Kadam 2017; Kan.

- **The Question/mystery:** How rigorous should the consenting process be for the resulting consent to be valid?

Introduction cont...

❖ **Some of the Rigor-related**

- How broad should consent be, e.g., in genomics research? (Petrini, 2009; Tindana &Vires, 2016; Ow et al. 2018; Warner et al., 2018).

- How much information should participants be given, e.g. in research involving bio-banking & data sharing? Lyoen &Hoeyer, 2005; Tomamichel et al., 1995).

- What is the best method and language to deliver such information (Marshall & While 1994; Edwards et al., 1998;Madsen et al. 2000; Betancourt & Jacobs 200; Matsui et al., 2007;Sarkar et al., 2010)
- The problem of vulnerability that usually conceals the lack of freedom in consenting (Iacono &Murray 2003; Meser et al., 2004; Verastegui 2006)
- Etc.

The problem

- Despite the existing institutional, national, regional and international guidelines on obtaining consent, in actual practice (field) researchers and research regulators feel that these guidelines are insufficient – Frustration about the inadequacy/insufficiency of existing guidelines.

Why this is so:

- From the official general ethical guidelines, researchers and research regulators seem to *always* expect direct answers to *all* questions and ethical dilemmas in the field. This unrealistic expectation explains the resulting frustration.

- **Implication of existing consternations:** Strict adherence to existing ethical guidelines *does not guarantee* the validity of the resulting consnent. ... Hence, obtaining *substantively* valid consent in specific studies may sometimes require departure from and addition to existing ethical requirements.

Task of the paper

- To provide conceptual tools by which to demystify the mystery about requirements for obtaining and ascertaining valid consent.
- The proposed concepts:
  - **Fact-skepticism**
  - **Rule-skepticism**
  - **Hypothetical Guidelines**
  - **Real Guidelines**
  - **Bioethical reflexivity**
- Once internalized and operationalized, these concepts will significantly mitigate frustrations met by researchers and research regulators in attempt to obtain and ascertain the validity of consent

The Concepts

1. ***Fact-skepticism:*** General ethical guidelines are made to apply on specific facts of studies, yet not all of such facts can be foreseen or predicted with fair certainty at the point of bioethics rule-making.

Facts include:

a)The type of study (e.g. Genomics research or clinical trials etc.)

b) Study design (e.g. Rondomized and placebo controlled studies etc.)

c) Demographic attributes of the community the study is taking place (incuding characteristics of target participants e.g, Children, pregnant women, Psychiatric patients, Socio-economic status, Religious beliefs, etc.

etc.

This reality of *uncertainty* about the actual facts of all future studies is what is referred to as ***Fact-skepticism*** at the point of rule-making.

The concepts cont ...

2. Rule-Skepticism: It is a corollary of fact-skepticism

- Since ethical guidelines are intended to apply to specific facts, then such rules are as skeptic (uncertain/inconclusive) as the facts on which they are based. The reality of *Rule-skepticism* can also be understood as *rule-insufficiency* or *rule-inadequacy*.
- The fact of our failure to foresee all the facts for which we are making ethical rules, explains why pre-determined general ethical guidelines *cannot always* be sufficient/adequate to guide the making of decisions which are always free of controversy.
- That's why it is an unrealistic expectation for researchers and regulators to expect to *always* get direct answers from these general guidelines to *all* specific questions that arise in the field.

The concepts cont...

3. *Hypothetical Guidelines*

- The truth of both *Fact-skepticism* & *Rule-skepticism* qualify the contention that existing guidelines are *Hypothetical* in character.
- **Reasons:** They are based on hypothetical facts and they are intended to:
  - Prevent recurrence of some gruesome historical scandals (which *might* recur)
  - Prevent unprecedented scandals but which we can reasonably predict or imagine
  - Regulate studies of different *possible* types and designs
  - All these are taking place in hypothetical communities & individual participants
- Consequently, pre-determined general ethical guidelines are as hypothetical as the facts on which they are based, the fact that further explains their inadequacy in real situations (in the field)

The concepts Cont...

4. The *Real Guidelines*: Since bioethics decision-making *cannot always dwell entirely* on pre-determined ethical guidelines, then the *Real Guidelines* are the *actual decisions on the ethical design of the study*, including the process of obtaining consnet.

- These decisions (real guidelines) are arrived at by researchers, with the approval of RECs/IRBs, in consultation with the local community.
- The sources of authority in this process are:
  - General hypothetical ethical guidelines
  - Specific type and design of the study
  - The specific demographic characteristics of local communities (including individuals)
  - The widely accepted cultural norms and beliefs of the concerned communities
- The wisdom of the researchers and their regulators (this needs a reflexive attitude and skill)

The concepts Cont...

5. Bioethical reflexivity: To arrive at *Real guidelines*, there is need for the concept and practice of bioethical reflexivity.

- **Reflexivity in abstract**: The habit of constant critical appraisal of one's intentions and means (including questioning established or dogmatic means &understandings) in light of certain goals (mainly in the construction of knowledge.
- On the basis of insights from Karl R. Popper's contentions in *The open Society and its enemies* (1945) and *The logic of scientific discovery* (1934), Soros George coined the «Human Uncertainty Principle» that necessitates the concept and practice of reflexivity (2013).
- **The point:** Given human epistemic fallibility, we cannot claim to know all the reality we need to in order to come up with rules/laws, whether social or physical, that always fully explain our current and future circumstances. Hence, we need reflexivity in order to reduce chances of error (Soros 2013).

The concepts Cont...

- **Bioethical reflexivity:** The disposition, habit and skill of ensuring rigour in the process of ethical decision-making, including ensuring the most worthwhile interpretation of existing guidelines and being able to fill the gaps left by such guidelines, using broader skills of moral reasoning in pursuit of morally appropriate decisions in given circumstances.
- **Accountability:** Bioethical reflexivity promises better ethical accountability

Reason: It is possible to strictly follow established guidelines but end up with dubious consent, or any other decision of moral significance. Besides, more than one ethical rule could potentially apply to a single case with different ethical implications etc. Bioethical reflexivity shifts the burden of proof away from mere rules to agents (researchers & their regulators) to demonstrate that indeed the decision reached was the best in the circumstances. This shift provides better service to the concept of «Responsible Conduct of Research».

Conclusion

- The problem about the process of obtaining and ascertaining informed consent is not that the guidelines are too general to always provide precise answers to all specific ethical questions/or dilemmas in the field. Rather, the proble is the lack of a reflexive attitude and skill to use existing general guidelines to arrive at specific decisions.

- So, on top of empirical research on the process of informed concent and listing the relevant ethical rules and guidelines, researchers and their regulators need to broaded and deepen their skills in abstract moral reasoning and practical moral decision-making, including critical thinking.

Other papers & activities

Paprers

1. *'Bioethical Reflexivity' and Requirements of Valid Consent: Conceptual Tools*
2. *Bioethical Realsism: A fremework for implementing universal ethics* (Fully accepted in Developing World Bioethics)"
3. *History of CIOMS and the recent changes in the international ethics guidelines: implications for local research ". Assigned Subject for opening plenary session at the UNCST's 10th ANREC, 10-11 July, 2018. (Publication Title:* The character of CIOMS/WHO ethics guidelines: Implications for local research).

Conferences

Access to medicines for neglected tropical diseases. Kings College Cambridge Global Health. 8th February, 2018.

Methods in applied ethics. 19 – 20th April, 2018. Norwegian University of Science and technology. Presentation title: *Bioethical Realsism: A fremework for implementing universal ethics*

Mapping Morality in Global Health 26 -27th June, 2018. University of Cambridge, **CENTRE FOR RESEARCH IN THE ARTS, SOCIAL SCIENCES AND HUMANITIES.**

Uganda's 10th Annual Research Ethics Conference. 10 -11th July 2018. Uganda National Council for Science and Technology, Kampala Serena Hotel. *History of CIOMS and the recent changes in the international ethics guidelines: implications for local research ".*

Other activities/Benefits

Seminar Presentation: 'Bioethical Reflexivity' and Requirements of Valid Consent: Conceptual Tools. **11th June, 2018. Department of History and Philosophy of Science, University of Cambridge.**

2 Pending seminars at Makerere University

Primary Data collection – Complted.

Networking with 10 bioethicists in the East African region

1. **University of Nairobi**
2. **Nairobi Hospital;**
3. **Strathmore University, Nairobi;**
4. **Muhimbili University, Dar es Salaam;**
5. **Hubert Kairuki Memorial University: Faculty of Nursing, Dar es Salaam.**