Double standards in research ethics

Case-studies:
Informed consent and Vaccine to treat Rotavirus

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Informed Consent reflects and contains values reflecting the importance of freedom and communication. The wording “informed free choice” could be more appropriate, to express “genuine consent”. The term consent is too directional.

- **Problem** Informed Consent (IC) has become a contractual tool, which originated in the US and EU. When used in other contexts, it might be countercultural: cultural tradition and values should be integrated in the IC process.

- **Action** A multicultural/multinational collaborative study of the acceptability of IC to explore this; to identify those countries where IC is not accepted and identify alternative value systems (e.g. communitarian or care approaches...). Contextualization occurs through dialogue and a stepwise approach. Integrating cultural tradition values should not weaken the principles and standards of the persons’ rights to be personally and fully informed.
Informed Consent

- **Problem** A community approach may lead to tension between the opinion of the local chief/authority and the individual’s consent.
  - **Action** Informed consent, in countries where a community approach is requested or preferred, as a rule should be a two-step process: opinion of the Chief and ultimate personal consultation and consent (full autonomy and empowerment of individuals). EU could fund a study to establish where community consent is preferred and why, and/or to explore best practices in community enrolment.

- **Problem** Adequacy of understanding: lack of understanding is not confined to developing country settings: it is found ubiquitously and is probably due to bad explanation/lack of dialogue (pushing the person to sign for speedy recruitment, legal concern as main priority).
  - **Action** IC is a continuous process, not a (quickly) signed sheet of paper. The responsibility for the process is shared (Sponsor, Investigators, EC, patients). A study could identify best practices in IC in developing country settings.
  - **Action** Need for ongoing forum for dialogue between sponsors, researchers, hosts, ethics experts and REC members, patient groups to explore and consider various approaches to enhancing quality of IC. EU could fund study of best practices to promote enhancement of understanding in IC.
Informed Consent

Who should assess the IC process? The EC members & PI should at least make *ad hoc* field visits.

- **Problem**: If it's deemed best in EU to have a common consent form and process, is it not a double standard to tolerate other forms in developing countries? There are probably double standards within developed world and developing world settings. When is a difference in a consent process a double standard?
  - **Action**: Funded scholarship for ethical reflection on this to identify ethically acceptable process.
What is “genuine consent”? Where is double standard in IC process?

Freedom to consent = freedom to refuse
Lack of available health care = not free to choose.

- **Problem** Research participants in developing countries often confuse incentives with benefits, thus unduly inducing consent and compromising voluntariness.
  - **Action** A study of the perceived voluntariness of those in health research where, whether and under what conditions voluntariness is maximised or compromised. Voluntariness seems a more important factor than understanding of Info.

- **Problem** It is always ethical to provide treatment in clinical research. However, it is ethically complex to bind access to a life-saving therapy to participation in a research (e.g., ARVs trials where there is no universal treatment). Treatment is conditional upon enrolment. Such consent is “biased” – voluntariness may be compromised by the benefits, yet it may be unethical not to provide benefits.
  - **Action** A study to explore ethical aspects of obligations to provide continued access to treatment for those who refuse or withdraw from studies in developing countries. What are the ethical obligations of researchers to those ‘screened out’ of studies or who decline enrolment, but who have no other access to care?
What is “genuine consent”? Where is double standard in IC process?

- **Problem** The ethical priority is to **ensure sustained access to appropriate (not a minimum) health care for all**. The search for knowledge of better care through the research start comes later.

- **Problem** The research must be **beneficial to the population** and the population must have **full access to the benefits** of the research.
  - **Action** There should at least be open access to scientific findings of all research.
  - **Action** Funding mechanisms should be explored to ensure better access to beneficial research outcomes, especially where public health access is poor.
Problem: Most RECs in DCs need core funding and ongoing educational materials.

Action: Find core funding for RECs in DCs:
- More materials for RECs
- Research/surveys to identify best practices of RECs in dealing with placebo issue
- REC Capacity building funding should be based on need assessments, and not be donor-driven (funding for needs assessments)
Monitoring

- **Problem** RECs almost universally are described as being under-resourced to conduct post-approval monitoring.

- **Action** Find resources to enhance monitoring capacity of RECs
  - Conduct research to establish real value (cost/benefit) or otherwise of monitoring in protecting research participants and ensuring protocol compliance
  - Research to determine optimal patterns of monitoring
Problem: The system of short REC training workshops has limited impact and this should be assessed before funding further training. We need an ethical research environment, a sustained system approach for collaborative research training and a continuous education with deep expertise in bio-ethics. How could it fit the agenda of the various ethics and bio-ethics bodies, to match the needs of the concerned countries?

Action: Study of impact of current training approaches and development of a data-driven approach to research ethics training that includes the cultivation of an ethical research ethos.

- EU should fund a consultation with NIH Fogarty and Wellcome Trust and stakeholders to find best model for building ethics training centres of excellence rather than short courses. Should probably focus on Francophone developing countries.
- Such grants should be planned as to encourage performance based grant renewals and continuity so that centres of excellence can be initiated and developed over the medium to long term.
Problem: Research environments lack ethical ethos; ethics seen and extrinsic.

Action:
- More training of all stakeholders (incl. patient communities) to cultivate ethical ethos in research environments. EU could learn from best elements of the Fogarty approach with a focus on developing country centers of excellence.
- Pharma and all other major research funders could be required to devote a % of funding to ethics capacity building of all research stakeholders.
Problem: No international professional association for REC members. This helps with professional development & career path.

- Action: Exploration of contribution to participant protections from such organisations – needs assessment research.
Are there researches that are unacceptable in the North and acceptable in the South?

- **Problem** Justifying a placebo arm, based on the fact that the existing effective therapy is not routinely available in the country.
  - **Action** EU funding of further consensus-seeking forums on definition of best standards and use of placebo.

- **Problem** Contextualizing a risk-benefit assessment (e.g. Rotavirus vaccine, fast track registration of ARVs in the 80’ and 90’)
  - **Action** To study the conditions which to justify exceptions (not a rule).

- **Problem** Double standards exist within developed and developing countries, depending on illness conditions, social status of participants, national health priorities.
  - **Action** Developed countries should address such double standards first before they try to eliminate double standards in the developing world; they will be more obliged to be consistent if there are no double standards at home.
Are there researches that are unacceptable in the North and acceptable in the South?

**Problem:** Ethical principles should be universal, but Plurality and respect for cultural difference is also a value.

- **Action** Need to contextualize the procedures and tools, in light of the cultural tradition, values and national laws, without weakening the ethical principles (e.g., right to unconditioned health care, personal autonomy etc.) and without accepting passively the status quo.
- **Action** Studies of what actually happens in contextualising ethics procedures in research in a random sample of studies in developing countries.
Which research in DCs?

- **Problem** Most research in developing countries is investigator-initiated, locally funded small scale studies. They cannot possibly ensure access to benefits. Is there a double standard in that benefits are only obligatory for large well funded studies?
  - **Action** Ethical analysis of this problem and exploration of possible remedies.