A Bioethics Study of Clinical Research in Malawi

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Project Rationale

- Widespread conduct of clinical research in Africa is creating a great demand for answers to questions of ensuring that research is conducted to the highest ethical standards.
- To date, there is **little** ethical and cultural knowledge that has been derived from **empirical research** in ethics (in Africa).
- There is a temptation to rush to give ethical answers based on principles and practices from elsewhere without deeply researching the local perceptions and attitudes in the developing world and specifically, in the **African context** where the questions are being asked.
- This project is based on the belief that in relation to ethical issues surrounding biomedical research conducted in developing countries it is simply not appropriate or justifiable to continue copying 'ready-made' answers from the West.

Objectives

- To improve understanding of cultural attitudes, beliefs and perceptions to research, community consultation and individual informed consent process in urban and rural settings.
- To provide a base for informing, reforming and improving informed consent policy and practice by describing the local cultural attitudes and perceptions to research, autonomy, informed consent process and community consultation.
- To assess validity of the Western concepts of informed consent and autonomy in an African setting.

Methods (1)

Study divided into three phases:

- Phase 1: Qualitative, an anthropological and cultural study;50 FGDs conducted with 494 participants from rural and urban settings. 5 categories of respondents : *participants, refusers, non-participants, local leaders, health workers.*
- Phase 2: Quantitative, a sub-study of on going clinical research; 318 interviews conducted with participants from 5 different clinical studies taking place in Blantyre (2 funded by Welcome Trust) and Lilongwe (3 funded by UNC).

Methods (2)

- Phase 3: Applied and comparative study; will compare findings from Phases one and two with findings from similar studies conducted elsewhere in Africa.
- Approval for the study was sought from and given by the College of Medicine Research Ethics Committee .
- Informed consent of respondents sought verbally in both phase one and two.
- Data was analysed both manually and electronically (N6 used in phase1 and statistical analysis used in phase 2).

Results (1)

- Most FGD participants described health research as activities associated with preventive health measures such as community assessment and health education
- While 94.6% (298) of the interviewees said they understood the study objectives, only 21.8% (65) could state them correctly.
- Among the category of *participants*, the need to receive “good quality” health care was said to be the motivating factor to participate in health research.

Results (2)

- During interviews, 30.9% (97) of those who perceived any benefits from their participation in the clinical research mentioned the “quality” of care provided as one of the benefits of participation.
- Individual consent was perceived as necessary before one is involved in health research with signing or thumb printing seen as the best method of giving consent; and 92% (294) confirmed their understanding of the informed consent procedure.
- 16.6% (52) acknowledged availability of risks to their participation in the clinical research.

Conclusions

- People who refuse to take part in health research, do so with an impaired understanding of its meaning and objectives because of superstitious rumors associated with health research e.g. blood sucking.
- Those who consent are able to differentiate between care and research but choose to participate in research to receive “good quality” care provided to research participants.
- Participants understand their voluntary participation in research and appreciate the individual informed consent procedures; with community consultation seen as customary.

Future perspectives

- Promotion of dissemination of research findings to communities
- Development of public sensitization program on research
- Development of materials in local language that can be used by investigators
- Conducting workshops for investigators and research assistants on the ethics of clinical research & principles of good clinical practice

Capacity building/Networking

- Introduction of bioethics modules into undergraduate as well as postgraduate curriculum at the College of Medicine.
- Introduction of MPH degree specializing in bioethics (CoM/MSU/Forgaty partnership)
- Training and strengthening capacity of the two RECs (EDCTP funding)
- Improvement of operations of COMREC (AMANET funding)
- PhD scholarship in research ethics (Wellcome Trust)