

Anthropological and Bio-ethics Study of Clinical Research

The Wellcome Trust

Title

Principal Investigator Prof. JM Mfutso-Bengo, University of Malawi
Head of Malawi Bio-ethics Research Unit (MABIRU)
Dept. of Community Health,
College of Medicine, Private Bag 360, Blantyre 3,
MALAWI.
Tel: +265-957805 or 265-1671911
E-mail: joseph-mathew@gmx.net,
mfutsobengo@medcol.mw

Collaborator/Advisor Prof. Malcom Molyneux
Director - Wellcome Trust Research Laboratories,
Blantyre, MALAWI.

Type of award Project

Duration 36 months

Start date 1 September 2003

Introduction

This research project is being conducted in three phases over three years:

Phase 1: **Anthropological and Cultural Study.**

Phase 2: **Bio-ethics Sub-Study of Clinical Research.**

Phase 3: **Applied and Comparative Ethics.**

Phase 1 - Anthropological and Cultural Study

The first phase comprises an anthropological and cultural study of perceptions and attitudes to research, autonomy, community consent and the informed consent process will take place in a rural and an urban catchment area where several research projects have been conducted there in the past 12 years. We intend to have about 600 research subjects participating in 50 focus group discussions composed of 6-12 people.

Rationale

1. To date, there is little research done in ethics in Africa. We wish to fill this gap by doing research in ethics to find appropriate local ethical answers through research in ethics. Being surrounded by many internationally-funded research institutes and such as the Wellcome Trust Research Laboratories, John Hopkins, University of North Carolina, Gates Malaria Alert Center, and University of Michigan malaria project, the College of Medicine in Blantyre

is in strong position to do research on ethics in ongoing clinical research in Africa.

2. The great demand for clinical research in Africa is creating many challenges with respect to research ethics. However there is a paucity of ethical and cultural knowledge derived from empirical research in ethics.
3. The growing number of cross-border research collaboration and funding are provoking new ethical questions of jurisdiction, of how to share the research benefits and risks, of justice, of how to obtain genuine informed consent, nature and degree of disclosure in clinical research.
4. The rapid drive of clinical research will continue to raise more ethical questions than it answers.

Aims

1. To improve understanding of cultural attitudes, beliefs and perceptions to research, community consent and informed consent process in urban and rural settings.
2. To assess the validity of the Western concepts of autonomy and informed consent in an African cultural and social context.
3. 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.

Methodology

1. The methodology for the anthropological and cultural study will adopt a community-based approach. Community meetings will be convened to explain the research project and identify those who participated or were invited to participate in clinical, medical or health research anytime during the past 3 years. These individuals will be invited to participate in the focus group discussions.
2. Special focus groups composed of community leaders, religious leaders, traditional healers and teachers will also be arranged. These special focus groups will include those who never participated in medical research.
3. The same pro-forma for the focus group discussions will be used for the anthropological-cultural study both in the rural study site and the urban study site. .

Phase 2 - Bio-ethics Sub Study of Clinical Research
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This second phase seeks to inform deliberation and resolution of ethical issues related to clinical research through empirical data obtained from research subjects who are already participating in ongoing research. Research subjects who are participating in an ongoing clinical study will be interviewed about their comprehension of informed consent, research, objectives, benefits and risks in a clinical study in progress at Queen Elizabeth Central Hospital,

Blantyre. Another comparable ethics study will be done in an ongoing clinical study in a rural health centre. Individual interviews will be conducted with approximately 400 participants.

Rationale

1. The perceptions of the research subjects involved in clinical trials¹ regarding ethical issues in human subjects research,² have not been widely studied or documented.³ In particular in Malawi, minimal data exist on: how participants are recruited and informed⁴; the extent to which participants understand specific research; the role of culture, poverty, traditional chiefs, community leaders in the individual informed consent process; the impact of this understanding on decisions to participate; participants' understanding of the nature of research and motivations for participating; and participants' understanding and beliefs.

Aims

1. To describe the attitudes and experiences of research subjects who receive information about enrolment in a clinical study regarding important ethical issues, such as the quality of the informed consent, the informed consent process, the reasons for choosing whether to enrol, and beliefs about stored tissues.
2. To describe how well the research subjects understand:
 - that the study is a research study;
 - the potential risks involved;
 - the potential benefits of participation;
 - the opportunities to decline to participate and withdraw;
 - the nature and purpose of the study.
3. To assess research subjects' reasons for choosing whether or not to enrol in a study, and the role of poverty, cultural beliefs, family members, and community leaders in the informed consent process.
4. To examine the research subjects' motivations and expectations related to a study.
5. To describe the research subjects' ability to distinguish research and standard and routine clinical practice.
6. To obtain demographic and health status information to describe the sample and stratify the data.
7. To compare findings arising from clinical study in hospital setting and a community in a rural setting to establish what underlying differences may exist because of setting-specific issues.

Methodology

1. For the Bio-ethics Sub-Study of Clinical Research, in-person interviews will be conducted. Participants will be recruited from the research rooms at Queen Elizabeth Central Hospital, and Lungwena health centre. Trained interviewers will conduct in-person interviews with research subjects who received information about enrolling in a clinical study, and who are participating in a clinical study or participated in clinical study in the past three months.
2. The survey instruments will consist of questions relating to the following domains:

- Informed Consent Process and Document
- Reasons for Enrolling in Research or for not enrolling:
- What matters more the trust or the benefits?
- Understanding of the Study
- Ability to differentiate research from medical care

Phase 3 - **Applied and Comparative Ethics**

The third phase will compare both the Anthropological and Cultural Study (Phase 1) with the Bio-ethics Sub-study of Clinical Research (Phase 2). We shall also compare the Malawian results with those from Kenya obtained by Sassy Molyneux, Ezekiel Emmanuel in Zambia and Paulina Tindana in Ghana. It is anticipated that the results will provoke further discussions, to improve the existing informed consent process and change existing informed consent policies and practices.

IRB Review & Human Subjects Protections

The studies planned for phase 1 and 2 have been submitted for independent review to the College of Medicine Research and Ethics Committee and received approval. Procedures for full ethical protection of subjects in this research have been designed and approved.

¹ Lynoe N, Sandlund M, & Jacobsson L, "Informed Consent: Study of Quality of Information Given to Participants in a Clinical Trial," *BMJ* 1991; 303: 610-3; Preziosi MP, Yam A, Ndiaye M, Simaga A, Simondon, F, & Wassilak, S, "Practical Experiences in Obtaining Informed Consent for a Vaccine Trial in Rural Africa," *NEJM* 1997; 336: 370-373; and Lynoe N, Hyder Z, Chowdhury M, Ekstrom L, "Obtaining Informed Consent in Bangladesh," (letter to the Editor), *NEJM* 2001; 344: 460-461.

² Both within individual countries and in multinational research.

³ Dal-Ré, R., "Elements of Informed Consent in Clinical Research with Drugs: A Survey of Spanish Clinical Investigators," *Journal of Internal Medicine* 1992; 231: 375-379.

⁴ See Williams, C.J. & Zwitter, M., "Informed Consent in European Multicentre Randomized Clinical Trials: Are Patients Really Informed?," *European Journal of Cancer* 1994; 30A(7): 907-910.