

The African Perspective on Global Research Ethics

Amos Massele MD, Ph.D
IRB Chairperson

Director of Research and Publications,
Muhimbili University College of Health
Sciences (MUCHS), Dar es Salaam,
Tanzania,

Introduction

- International Collaborative research in Africa and other developing countries has been on the increase in the past decade
- The African Scientific Community has found itself facing some ethical issues when conducting researches in Africa

- HIV/AIDS pandemic, has initiated a new debate on ethics in terms of treatment, testing of new medicines and vaccines
- There is also difficulty in eliciting informed consent in a illiterate population in Africa

Intro...

- Africa presents many challenges when it comes to the application of the ethical principles like:
 - Respect for persons
 - Beneficence/ Non maleficence
 - Justice

- It is important that the nature of the society to be investigated must be clearly understood by scientists intending to conduct research on HIV/AIDS
- In this presentation, I will highlight African perspective on global research Ethics in the context of "Universal Ethical Principles"

Ethical principles and ethical guidelines in African Societies.

- Concerns are being expressed about the validity of applying **international** ethical principles that may be questionable in an **African culture**.
- This sometimes creates friction especially in International collaborative research
- A Western collaborator may have totally different ethical approaches which may be unacceptable in African communities
- Eg in some African cultures decisions to consent are made by heads of households on behalf

- The following are some characteristics of African Societies, which render them potentially vulnerable to exploitation in the conduct of research:
 1. Poverty (low levels of economic capacity)
 - In African Societies poverty may be a reason to consenting to participation
 - An individual may agree to participate under the expectation of getting financial gains
 - However the ethics only allows free consent without coercion
 - Compensation can be made only in terms of time, fare and other unforeseen costs

2. Illiteracy therefore creating difficulty in eliciting informed consent
3. Limited understanding exposures of a given scientific research
4. Limited local infrastructures eg research centers and other facilities
5. Capacity for providing health care and treatment options in research participants

6. Limited experience and capacity for conducting ethical and scientific reviews
7. Civil wars, famines, floods and other man made disasters that make the obtaining of individual informed consent challenging

The African perspective on Global Research Ethics

- Various sets of International research ethics guidelines exist
- The most widely consulted sets include the declaration of Helsinki, the council for International organizations of Medical Sciences Guidelines and the Guidelines of Good Clinical Practice.
- These guidelines were primarily developed in response to the way medical research is conducted in developed countries

- In Africa, Asia and Latin America, these guidelines may be of limited relevance
- Because of the differences in terms of literacy, poverty levels & economic status
- In addition social cultural differences among communities in developing world create difficulties in operationalising the laid principles involving human subjects e.g.
Informed consent

Informed consent

- The requirement to obtain voluntary informed consent from human participants before they are enrolled in research is a fundamental requirement
- Informed consent was one of the requirements proclaimed in the Nuremberg code and thereafter in the Declaration of Helsinki on research ethics involving human participants.

Informed consent...

- In Africa, there is debate about the value and importance of some approaches to informed consent
 - some participants may be incapable of understanding information needed to give a voluntary informed consent because of illiteracy
 - In some African societies for religious reasons, male researchers cannot interview women and only husbands can consent on behalf

Informed...

- It is therefore a fact that some of the interpretations and methods used in Western countries in obtaining informed consent might not be appropriate for Africa because of different cultural or social norms.

Informed consent...

- International ethics require a dialogue between a researcher and only a person being recruited
- This brings problems in an African setting where an **individual** is viewed as a part of the **society**
- In such cultures a person is closely related to others, such as the extended family

- Therefore there is a gap in the application international ethics in African social cultural settings
- Considerations must be addressed to fill in this gap
- Confidentiality issues in African cultures is also a problem

- In Africa a potential participant (HIV/AIDS patient) may not be willing to disclose his HIV sero-status to the community leaders
- The ethical procedures require that ethical approval to conduct the study also be obtained from the village leaders and other community authority

Consent...

- The community authority must be informed on the target group so as to enable sensitization
- Thus violating confidentiality
- This contributes to low number of subjects consenting to participation in HIV/AIDS related studies

- In addition international guidelines often focus on informed consent requirements and requiring both written and verbal consent
- This may be difficult to implement in illiterate African communities and in some oppressive regimes in Africa

Recommendations

- African ethics review committee need to be given flexibility by Western collaborating institutions over the documentation of informed consent in accordance with local cultural norms

Therapeutic misconception

- Studies in Africa on informed consent especially in the context of HIV vaccine trials and microbicides require serious attention
- Participants in such trials develop a false confidence and feel that they are protected against infectious and engage themselves in risky behaviors
- Researchers in Africa need to deal with this and come up with ways of disclosing information that ensures that participants are well protected

Summary on informed consent

- In Africa therefore, informed consent is complex and involves complex interactions between moral values, cultural and political values
- Informed consent needs to be formed on the basis of cultural appropriateness and acceptability
- Upholding the principle for respect of persons should not only entail respecting the individual but should take into consideration their cultures and traditions

Clinical trials in Africa

- ❖ A clear policy is needed on the subjects benefit on the findings of the study
- ❖ What happens to participants once the project is completed-Is there any long term follow up of the participants
- ❖ should the treatments found successful be made available on long term to the participants ???

Conclusion

- Research in Africa should depend on local ethics committees to determine if the research is warranted and whether it is exploiting the poor and vulnerable

Acknowledgements

- To organizers and sponsors of this workshop.

Thank you for listening