CROSS CULTURAL ETHICAL PERSPECTIVES IN HIV CLINICAL TRIALS

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Key areas

- Basic ethical principles
- Risk benefit assessment
- Informed consent
- Selection of subjects for research
- Benefit sharing

Basic ethical principles

- Respect for persons- respect my decision
- Beneficence- keep me from harm
- Justice-who ought to receive the benefits of this research and bear the burden?

Basic ethical principles-translation

- Respect for persons- Informed consent
- Beneficence- Risk benefit assessment
- Justice-selection of study subjects and benefit sharing

Informed consent allows individuals:

- To determine whether participating in research fits with their values and interests.
- To decide whether to contribute to this specific research project.
- To protect themselves from risks.
- To decide whether they can fulfill the requirements necessary for the research.

Informed consent

- Competent person- ability to make sound judgment
- Disclosure of relevant information- Inform clearly
- Understanding of this information- comprehension
- Voluntary decision whether to participate- no inducements or coercion

Cross cultural issues around consent

- The concept of community rather than the individual.
- Ethics require that the individual gives consent.
- How can this be balanced in a culturally sensitive manner.

Risk benefit assessment

- Risk refers to possibility that harm may occur
- Benefit refers to the positive value related to health or welfare
- Risk assessment is concerned with the possibilities and magnitude of possible harm and anticipated benefits
- Risk and Benefits must be balanced and shown in favorable ratio

Risk benefit assessment

- Protection against infection?
- Protection against severe disease?
- All in all the benefits should outweigh the risks

Cross cultural issues: Risk benefit assessment

- “Doctor” knows best mentality.
- Importance of capacity of IRB’s to make informed decisions.

Selection of subjects for research

- Principle of justice require that researchers exhibit fairness
- Injustice may occur with vulnerable groups e.g. economically disadvantaged, the very sick. These groups may be manipulated as a result of their illness or socioeconomic condition.

Cross cultural issues: Selection of study subjects

- Vulnerability
- Poverty
- Coercion
- Undue inducements

Declaration of Helsinki 2000

- “Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.”
  - Paragraph 19

What should be made available?

- Do sponsors, researchers, or ministries of health have an obligation to the community or country if a successful product results from a vaccine trial?
- Some current answers….

Highest attainable level of care

- UNAIDS Guidance Point 16: Care and treatment
  - Care and treatment for HIV/AIDS …should be provided to participants… with the ideal being to provide the best proven therapy, and the minimum to provide the highest level of care attainable in the host country in light of [circumstances specified].

Benefit sharing

- CIOMS:
  - “ As a general rule, the sponsoring agency should agree in advance of the research that any product developed through the such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing”

Benefit sharing

- How strong should the commitment be at the beginning of the study?
- To whom should the vaccines be made available?- study participants, study area, country!
- Reasonable availability does not always protect against exploitation

Fair benefits: the better option

- And the fulfillment of the following additional principles:
  - Fair benefits
  - Collaborative partnership
  - Transparency

Fair benefits: the better option

- Underscores the following key areas:
  - Must address a health problem in the developing country
  - The research objectives and not the vulnerability of the populations must provide a strong justification of carrying out research in that population
  - The benefits to the participants involved in the study should clearly outweigh the risks

Fair benefits: the better option

- Whilst availability of a safe and effective intervention may provide important benefits for the trial once it is over. There may be other post research benefits which include:
  - Capacity Development
  - Enhancing health care and health facilities
  - Providing critical equipment
  - Profits from direct sales of proven interventions

Fair benefits: the better option

Three broad types of benefits

- Benefits to the research participants during the trial
- Benefits to the population during the trial
- Benefits to the population after the trial

Benefits to the Participants before the trial

- Improvements to health and healthcare
- Collateral health services are not critical for the research study

Benefits to the Population during the trial

- Collateral health services
- Public health measures—e.g. wells and mosquito nets
- Employment and economic activity

Benefits to the Population after the trial is over

- Reasonable Availability to drugs and vaccines
- Capacity development—physical infrastructure, training
- Public health measures
- Long term research collaboration
- Financial rewards—IPR

Collaborative Partnership

- Community involvement at all stages
- Free uncoerced decision making by population bearing the burdens of research

Transparency

- Central publicly accessible repository of benefits agreements e.g. WHO
- Process of community consultations

Important issues for Africa

- Clear guidelines on the ethical and regulatory approval process for vaccine trials
- Increase capacity for ethical and regulatory review
- Promote sharing of best practices
- Have common agreements to decrease IRB shopping

Important issues for Africa

- Document and share experiences with the fair benefits framework
- Have an African repository for formal and informal agreements on research benefits.

Thank you