National Cancer Institute

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The ethics of clinical research: do they differ between high-, medium, and low-income countries?

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December 5, 2014, Melbourne, Australia

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Do the ethics of clinical research differ between countries of different resource levels?

- No

Principles underlying clinical research

- Principle of economy:
  - We want to maintain health, prevent disease, screen for, diagnose, and treat disease and its symptoms as effectively as possible with finite resources.
- Principle of urgency:
  - We want to find better ways to maintain health, prevent disease, screen for, diagnose, and treat disease and its symptoms as soon as possible.

What is clinical research?

- Broad spectrum of different types of research
- Added risk to participants from low to high
  - Epidemiologic case-control study with biospecimen collection
  - Prospective cohort study with biospecimen collection
  - Phase IV study of an approved medicine
  - Behavioral research study (such as tobacco prevention)

Added risk to participants from low to high

- Behavioral research studies (such as tobacco control)
- Cancer screening trials
- Phase III trials comparing standards of care
  - Screening, treatment, etc
- Phase III trials comparing standard of care +/- new agent
- Phase II trial of new drug or new combination of drugs
- Phase I trial of new combination of drugs
- Phase I “first in human” trial

Key elements of clinical research

- National level
- Level of local university, hospital or clinic
- Level of educational institutions
- Communications and awareness of clinical research

National level

- Understanding and commitment to clinical health research at Ministry of Health, Ministry of Science, civil society, educational institutions, and medical professional societies
- Funding for public/academic clinical research
  - Government/charity/institutional support
- Timely scientific review
  - Principle of urgency

National level: II

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  - Principle of urgency
  - Central review for multi-institutional trials
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  diagnostics needed for the clinical research
  - May require importation
- Support for biobanking
- Support for core laboratories

National level: III

- Facilitation of biospecimen transfer to core regional or global laboratories as appropriate
  - Principles of economy and urgency
- Support for national & provincial cooperative research groups
  - We need to study diseases and interventions in urban and rural settings, across different levels of socio-economic status, and among people of different ancestries and cultures
- Partnership with advocacy groups
- Partnership with industry

Communications and awareness of clinical trials

- Policy makers
  - Ministry of Health, Ministry of Finance, Ministry of Science, drug and device regulatory authorities
- Leadership of hospitals, universities, and research institutes
- Health care professionals
- General public
- Patients and their families
- Feedback of research results

Education about clinical research

- Theory and practice of clinical research should be part of basis curriculum at schools of medicine, nursing, and pharmacy
- Training for biostatisticians at bachelor's, master's, and PhD levels
- Advanced training for doctors, nurses, and pharmacists on clinical research
  - Master's degree level; fellowship level

Education about clinical research: II

- Training for ethics committee members
- Training on conduct of clinical research through medical professional societies
- Weekly lecture series on principles of clinical research at hospitals, universities, and clinical research institutes
- Training for advocates on clinical research

Involvement of advocates in clinical research

- Examples from US
- Coalitions of advocacy groups promoting support of research to policy makers
- NIH & NCI Director's Consumer Advisory Boards; National Cancer Advisory Board; President's Cancer Panel
- Advocacy participation in scientific planning, peer review, development of educational materials, etc

Principles of medical ethics

- Autonomy
- Beneficence
- Non-malificence
- Respect for human rights
- Justice
- Truthfulness and honesty

Global ethical guidelines for clinical research

- World Medical Association
  - Nuremberg Code, 1947, on human experimentation
  - Declaration of Geneva, 1948, on medical ethics
  - Declaration of Helsinki, 1964, 7th revision
- Council for International Organizations of Medical Sciences (CIOMS)
- International Conference on Harmonization (ICH)
  - US FDA, European Medicines Agency, Japan PMDA
  - Good Clinical Practice

Critical issues for all countries

- Timeliness of protocol development
  - Principle of urgency
- Timeliness of ethical reviews
  - Principle of urgency
- Consistency of ethical reviews
  - Central review for multi-institutional studies
- Feedback of research results
  - Principle of truthfulness & honesty; partnership

Informed consent process

- Process not a document
  - Do not follow US model!
  - May need permission of community leaders and/or family members
- What are the risks and benefits of participation in the research?
- What are the requirements in time, testing, and visits associated with the research?

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