

Challenges of Global Pharmaceutical Research

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*Teaching Global Pharmaceutical Policy
AACP Annual Meeting, July 20, 2009*

What's Different?

- Design
- Conduct
- Ethics
- Use of results



Clinical Research in Lesotho

- Bionor Immuno, biotechnology company from Norway → immune-boosting vaccine for HIV/AIDS.
- IATEC (Amsterdam) is CRO for this study, who approaches MOHSW.
- “Exploratory Study of Peptide Immunisation in Patients with HIV”

Exploratory Study of Peptide Immunisation in Patients with HIV

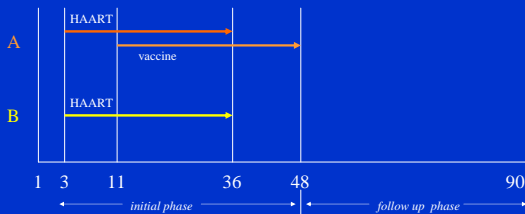
- Primary Objective: to compare clinical benefit (CD4 and viral load) between patients treated with immunotherapy and HAART (arm A) and those treated with HAART alone (arm B).



Exploratory Study of Peptide Immunisation in Patients with HIV

- Secondary Objective: to monitor safety and tolerability
 - Initial phase: [weeks 3-48]
 - Clinical adverse events
 - Signs of organ toxicity (blood tests)
 - Follow up phase: [weeks 49-90]
 - Recurrence rate and magnitude compared to pre-HAART levels (CD4 counts)

Exploratory Study of Peptide Immunisation in Patients with HIV



Research Designs

- Clinical research (how drugs work)
- Health services research (how drugs are used)
- Social-behavioral research (how to assess and increase adherence)

Generalizability

- US data: is it generalizable globally?
- If not, how to obtain local data



Data Integrity

- Research vs treatment
- Protocol vs trial & error
- Busy clinical practice
- Who collects research data?



Research Regulations and Ethics

- US-centric
 - Belmont Report/Belmont Principles
 - FDA regulations
- Global perspective
 - Declaration of Helsinki; CIOMS; WHO
 - ICH and country-specific regulations



BELMONT REPORT



3 Ethical Principles

- Respect for Persons
- Beneficence
- Justice

Sue's Grandma's Ethical Code

- Show Respect
- Do the Right Thing
- Be Fair



Ethical Codes for Human Research

- Nuremberg Code
- Declaration of Helsinki
- Belmont Report
- CIOMS
- Canada's Tri-Council Statement
- ICH
- Indian Council of Medical Research
- Nuffield Council
- WHO: International Ethical Guidelines for Biomedical Research Involving Human Subjects



<http://bms.brown.edu/fogarty/codes.htm>

Declaration of Helsinki

- 18th WMA General Assembly, Helsinki, Finland
June 1964
- 29th WMA General Assembly, Tokyo, Japan
October 1975
- 35th WMA General Assembly, Venice, Italy
October 1983
- 41st WMA General Assembly, Hong Kong
September 1989
- 48th WMA General Assembly, Somerset West, RSA
October 1996
- 52nd WMA General Assembly, Edinburgh, Scotland
October 2000
- 59th WMA General Assembly, Seoul, Korea
October 2008



Council for International Organizations of Medical Science (CIOMS) Guidelines



- Informed consent
- Research in developing countries
- Protection of vulnerable populations
- Distribution of burdens & benefits
- Role of research ethics committees

International Conference on Harmonisation (ICH)

- Standardize drug development & approval process
- Protocol development and analysis standards
- Review by research ethics committees
- Researcher responsibilities
- Sponsor responsibilities

National Regulations Vary





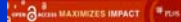
- Prior approval by research ethics committees
- Written informed consent
- Equitable recruitment of research subjects
- Special protections for vulnerable populations
- Continuing review of approved research

Process of Research → Policy

- Identify problem
- Ask research question(s)
- Design studies-work with stakeholders
- Results from one study inform the next
- Publish in accessible journal
- Work with health ministries/WHO to change or implement policies

Example: No-Shots

- Children die from severe pneumonia
- How prevalent is the problem?
- Why do they not receive treatment?
- Does oral therapy work as well as parenteral? In whom?
 - In hospital
 - Home vs hospital
 - Urban vs rural
- What should policy be?
- How can policy be disseminated?
- How can policy be implemented?










Challenges in Teaching Research Design & Research Ethics with a Global Perspective

- Include global ethical codes
- Research integrity
- Generalizability of results
- Dissemination/implementation of results

Summary Question

- Would you enroll your family member in this study?

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