Review of Non-National (International) Research Conducted in Less Developed Countries: Challenges and Opportunities

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Outline of presentation

- Research in context... (the KMC)
- What is int’l research?
- Why are developing countries targeted by int’l research?
- Why do ethically worry about “foreign research”?
- Challenges facing ethical review of int’l research
- Few suggestions to go ahead
- Take home messages
Research in context...the KMC

Knowledge Management Cycle

- Research
- Statistics
- Generation
- Assessment
- Dissemination
- Results
- Utilization
- Synthesis
- Evidence
- Clinicians
- Policy makers
- Cochraine EMBase
- Publications Conferences
Better Ethics for Better Health?

“Good” research: Good Science & Good Ethics

“Good” Evidence: near-top to hierarchy of Evidence

Evidence-Based Healthcare: Better practice that is based on best evidence

Better health status
Is it always that perfect?

The drug trials business in developing countries

Bioethics commission rules Guatemalan STD research unethical
by Jared Yee | 31 Aug 2011 |

It is estimated that 20-30% of developing countries. The reality is that it provides the means to obtaining a license to markets.

The drug industry is increasing companies are enrolling uninformative health studies. As a developing country, India has a targeted population. All the top names in the pharmaceutical world have facilities in major Indian cities, especially Hyderabad. A consultancy McKinsey & Co estimates that by 2010, they would spend around $1-1.5 billion just on drug trials.

US researchers violated ethical boundaries when they deliberately infected Guatemalan prisoners, mentally ill health patients, and prostitutes with sexually transmitted diseases in a 1940s research project, a presidential commission concluded on Tuesday.

Nigerians sue Pfizer over test deaths

Pfizer tested Trovan in Nigeria in 1996. A group of Nigerian families has sued the drug giant Pfizer following the deaths of 11 children and injury to others who are said to have taken part in tests of a drug to treat meningitis.

The group argues that the tests of Trovan, an antibiotic, were the cause of the deaths and injuries.
Where are we now?

Territory size shows the proportion of all scientific papers published in 2001 written by authors living there. Source: www.worldmapper.net
What’s int’l research?

- It is any form of systematic collection of human data or biological specimens that aims at producing generalizable knowledge;
- that is partially or fully funded and/or conducted by researchers or research institutes from outside the country within which the research or part of the research is taking place.
Why are poorer countries targeted?

- The comparatively low cost, less troublesome trials
- The high burden and variety of diseases
- Weak national review & judiciary systems (laws & courts)
- Lack of national research agendas & fund
- Facilitated e-communications (easier remote monitoring)
- Abundant, less-educated, more compliant subjects
  
  “We can recruit a third more patients, in a third less time and we can save at least a third of the cost”, Vijay Kumar, Neeman Medical International

- Political and economic corruption
Why would it be ethically troublesome?

- Poverty & ignorance make participants exploitable
- Host countries take more burden/harm than benefit
- The irrelevance of the study objectives or methods to the studied population
- Cultural & communication barriers (consent?)
- Commercial and academic agendas → COI
- Lack of adequate governmental protection to participants
- Research benefits are NOT adequately shared with researched communities
Challenges to review of int’l research in LMICs

IRBs/RECs
- Lack of staff
- Lack of training
- Lack of facilities
- Lack of capacity
- Lack of visibility (no website!)

Local Researchers
- Lack of fund (seek foreign)
- Lack of national research agenda
- Lack of training on REX
- Lack of experience with REXI
  • Intl’l researchers
- Lack of knowledge about local regulations & communities
- COI & Commercial interests

Socio-Political
- Illiteracy
- Lack of knowledge of personal rights
- Over-trust in doctors, especially foreigners (khawaja)
- Corruption
- Insecurity (research in Darfur?)

Regulations/Laws
- Not in place
- Not updated (IPR?)
- Not affective
- Not binding
- Of local effect/power

Reduced review ability
### Opportunities *(Who should do what?)*

<table>
<thead>
<tr>
<th>Universities, research centers</th>
<th>Researchers</th>
<th>Health facilities</th>
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</table>
| • Develop guidelines and policies | • Have training on REX  
• Know institutional & national guidelines  
• Know the review process (steps & duration)  
• Apply early  
• National researchers should be involved  
• Makes sure their participants are protected | • Train staff on REX  
• Establish local review mechanism  
• Establish research units/departments  
• Follow-up the studies conducted within their premises  
• Raise awareness among their clients  
• Control group receives an established effective treatment |
| • Train researchers on REX | | |
| • Train some staff on review & follow-up | | |
| • Develop & update research priorities | | |
| • Involve communities in research planning | | |
### Opportunities *(Who should do what?)*

<table>
<thead>
<tr>
<th>Research Ethics Committees/Boards</th>
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<tr>
<td><strong>Capacity building</strong></td>
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<td>- Training (long-term, short courses, on-job training, online certificates)</td>
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<td>- Staffing (No. &amp; qualifications)</td>
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<td>- Facilities (phone, internet, fax)</td>
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<td>- Fund-raising</td>
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<td><strong>Documentation</strong></td>
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<td>- Develop &amp; update guidelines</td>
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<td>- Develop clear policies and procedures (e.g. time, type, fees of review)</td>
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<td>- Increase transparency: Go visible <em>(if Google can’t find you, nobody will!)</em></td>
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<td>- Databases and registries</td>
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<td><strong>Collaboration, Advocacy &amp; Networking</strong></td>
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<td>- Bridge the MOH-Academia gaps</td>
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<td>- Communicate with other govt./private partners</td>
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<td>- Involve peripheries (states, governorates, regions)</td>
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<td>- Build Regional (MENA, EMRO) &amp; Int’l networks</td>
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<td>- Talk to law makers</td>
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Empower your country by int’l research

Accept ONLY int’l research that:
• Addresses research questions of national benefit
• Has a local partner (university, research center)
• Builds research capacity of the national partner (e.g. provide equipment)
• Has training component
• Has national/local co-investigators
• Provides service (or other benefits) to studied communities
• Abides to signed contracts & agreements (e.g. for local result sharing, IP rights, patenting, sharing research benefits)

Remember: You have the legal power to let a research go or stop!
Take Home Messages

- **Research** is only the means to better health through better knowledge – not an end in itself.
- **Research ethics** guides research to develop science with the least harm (& max. benefit) to its participants.
- **Int’l research** is NOT a threat unless our research systems are too weak to benefit from it.
- **To empower** our review capacity we need: self-development, communication, collaboration and partnerships.
Questions & Discussions

Thank You