Establishing International Health Research Collaborations

Tuberculosis Research in the Americas
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Objectives
- Describe different models of international health research collaborations
- Share lessons learned on successful international health research collaborations
- Share sources of international health research funding

Definition of Research
- "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
- Important definition for U.S. IRB

Types of International Health Research
- Basic biomedical research
- Public health: epidemiologic population-based research
- Translational research
- Implementation research
- Operational research
- Evaluation research

Collaboration Definition
- Jointly developing/agreeing on set of common goals and directions, typically an intellectual endeavour
- Sharing responsibility for obtaining those goals
- Sharing knowledge, learning and building consensus i.e. working together to achieve those goals, using the expertise and resources of each collaborator
- Collaboration does not require leadership and can sometimes bring better results through decentralization and egalitarianism

Why International Health Research Collaborations
- Technical exchange
- Capacity building on both sides
- Eliminating health disparities
- Investigating a rare disease
- Containing a disease at its source (MDR TB)
- Novel Ideas
- Sentinel surveillance
- Performing research in best site possible
  - E.g. malaria vaccine in malaria endemic countries
Challenges of International Collaborations

- International
  - Crossing many types of boundaries
  - Conflicting research philosophies, concepts & methods
  - Imbalances in capacity and infrastructure
  - Communication challenges
  - Country culture
  - Harmonization of working cultures
  - Language
  - Flow of funds, transparency and accountability
  - What is the measure of success?
  - Incentives may differ
  - Who is PI or the team leader?

Challenges of international Collaborations

- Collaborations
  - Competition, rivalry and turf issues
  - Politics
  - Institutional expectations and working culture (harmonization of cultures, academic, corporate, NGO, villages and within same type of organizations: academic to academic...)
  - Who is the PI? Differing concepts of “leadership” and team work

Establishing an International Research Collaboration: How?

- Networking, and personal contacts
- Ideas and preliminary data
- Sources of funding (seed grants, other)
- Mentorship approach, requires seed funding
- Institutional approach versus investigator-led approach
- International students alumni databases in the U.S.
- What about researchers databases abroad?
  - Some may have seed funding
  - Some countries have U.S. technology transfer seed funding

Number of New GHRC in the U.S.

- Fogarty alone has funded > 26 U.S. & international Global Health Resource Centers
- Not-Fogarty funded: > 10
- Many international health centers in U.S. creating databases of researchers interested in international health research and many have seed funding for travel to allow US potential collaborator to travel abroad and establish contact

What Does a U.S. University Investigator Need?

- A reliable collaborator(s)
- Access to local data
- Understanding the infrastructure
- Understanding the country’s health priorities
- Navigating the process
- Involving the right institutions
- Publications
- Academic recognition & promotion
- Being PI or co-PI
- Funding
- IRB requirements
- Other

What About the Host Country Investigator?

- Technical training and continuing education
- Capacity Building
- The right collaborator(s)
- Access to sources of funding
- Grant writing skills
- Access to journals
- Publications
- Academic recognition & promotion
- Independence
- Other
Basic Ingredients for a Successful Collaboration

- Shared Vision
- Mutual Respect
- Funding that renumerates both sides
- Understanding of Socio-cultural Issues on both sides
- Leadership & Team Work
- Initiative
- Diplomacy and a Positive Attitude
- Frequent, clear and open communication (email, phone and face time)

Measure of a Successful Research Collaboration?

- Number of co-authored papers
- Funding
- Public health significance
- Capacity building
- Independence or healthy co-dependence
- Sustainability

The Players in International Research Collaborations

- NGOs, Foundations e.g. Gates
- Universities
- Pharmaceutical companies
- Government organizations: e.g. USAID, CDC
- Multinational organizations: WHO, WB
- Various combinations including public-private

Examples of Models of International Collaborations

- “Business” model (RX)
- Postal/Parachute Model (Universities, Consultants)
- “Annexed sites” (Universities)
- Foreign AID model (USAID/NGOS/Universities)
- Mentor-mentee relationship model (Universities)
- Equal partnership model (Universities)

“Business” Model

Institute OneWorld Health: Non-Profit Model

- Identify potential new medicines for disease disproportionately affecting developing countries
- Assess safety & Effectiveness
- Establish Collaborations with partners to manufacture and distribute new medicines
- Ensure medicines affordable and available for distribution
- Programs: Visceral leishmaniasis, diarrheal disease, malaria, chagas

“Business” Models

Global Alliance for TB Drug Development (TB Alliance)

- Industry, NGO's and foundations > 30 partners around the world to accelerate the discovery and development of cost-effective new drugs
- Major TB Alliance partners include: Novartis India, the Bristol-Myers Squibb Foundation, the Association of British Pharmaceutical Industry and other pharmaceutical organizations, the Global Forum for Health Research and the Bill & Melinda Gates Foundation.
**“Business” Models**

- **Global Alliance for TB Drug Development (TB Alliance)**
  - In 2002 the TB Alliance in-licensed a promising new compound, PA-824 with potential for a new TB treatment, from Chiron and will be undertaking further pre-clinical studies shortly.
  - In March 2005, GlaxoSmithKline and the Global Alliance for TB Drug Development (TB Alliance) announced a joint discovery partnership to improve the treatment of tuberculosis (TB). The program substantially enhances the worldwide TB drug pipeline by adding several novel classes of compounds that use new mechanisms of action.

**Universities**

- Individuals
- Institutional

**Mentor-Mentee Relationship**

- **Mentee**: Students or individuals shifting careers
- **Mentor**: Investigators with complementary or needed technical skills
- **How to get a mentor?**
  - Student thesis
  - Seed funding that compensates mentor
  - Ability for Mentor to generate data for future research

**Postal Investigators & Annexes Sites**

- Not much infrastructure development (i.e., simple laboratory tests for example performed in US instead of foreign institution)
- Staff local with expat as head with differential salary lines
- Attracts best and brightest away from national research institutions and may result in drain of local government resources
- Not much emphasis on capacity building or sustainability

**Equal Partnerships**

- Both teams are involved in the whole research process
  - Conceive the idea and refine together
  - Develop the proposal together and provide feedback
  - Perform the research together
- Advantages: more likely to yield better results, reduce costs, improve communication, build a sustainable relationship and build capacity

**Equal Partnerships**

- Need both partners to have comparable technical or research ability: i.e., complementary skills
- Members need to share status, have a common language, and have clear expectations and leadership
**Case Studies**

Examples of Research Sites Abroad

**International Health Division: Egypt**
- UMB site in Cairo housed in the National Hepatology and Tropical Medicine Institute
- Hub with many partners including universities
  - >30 employees and office manager with financial team, data management team, research teams (hepatitis, cancer, smoking, injury, ethics), laboratory infrastructure with molecular biology research, cars, drivers...
  - Ability to perform clinical trials, surveys, case-control studies
  - 20 years: USAID funding schistosomiasis, Wellcome trust grant: mother and child infections, NIH grants (HEV, smoking, injury, ethics), European grants
  - >300 trainees including PhDs, Postdocs
  - More than 100 publications

**Egypt: Limitations**
- Infrastructure still very reliant on U.S. or outside funding
- While many Egyptian collaborators able to write their own grants and Co-PI or PI, infrastructure not yet fully independent on its own

**Emerging Pathogen Institute: NIH Morocco**
- Morocco NIH (CDC equivalent) and Emerging Pathogen Institute, UF: TB collaboration
- Needs on the U.S. side MDR, rare diseases
- Needs on Morocco side, technical exchange
  - Epidemiological studies
  - Latest tests and quality control
  - Clinicians input

**Challenge of Research Infrastructures**
- Individually maintained: sustainability?
- Dependent on outside funding
- Can it be institutionalized?
- How?
Impact on Health: The So What Question

- Sustainability and public health training versus just research collaborations
- Challenge: how to meet community needs yet address the predetermined categorical lines of fundings/solutions
- Developing nations contribution to scientific literature typically very low (< 1% according to one article)

CDC-CARE Health Initiative Model

- Robert W. Woodruff Foundation $5 million to CARE & CDC to create a sustainable partnership in global health
- Community-participatory research process: community partners, NGOs
- Grants based on projects identified by community
- Lima, Peru, a CCHI team worked with the urban municipalidades (local jurisdictions) on environmental health plan addressing unsafe drinking water, lack of sanitation, poor air quality, and other environmental problems.

ICDDR,B: Bangladesh

- ICDDR,B: not a government institution
- Combines basic and community based research in family planning, HIV, Cholera. Performs demographic surveillance
- Run by a whole lot of local and foreign donors
  - Foreign Director: David Sacks since 1999
- Over the years, center supported by 52 nations and organizations including universities

A Brief History of ICDDR,B: Centre for Health and Population Research

- 1960 Cholera Research Laboratory established
- 1968 First successful clinical trials of Oral Rehydration Solution
- 1971 Independence of Bangladesh
- 1978 Government of Bangladesh Ordinance establishing ICDDR,B signed
- Received UNICEF, USAID, and Gates Award for Global Health

ICDDR,B: On Sustainability and Independence: Interview with Sacks

- Success
  - Clear mission
  - High quality of scientific research, medical services and training
  - International character: Bangladesh and international professionals
  - High ethical standards
  - Transparent and reliable financial system
  - Dedicated and well trained staff, and
  - Consistent support from many donors and most importantly
  - Government of Bangladesh support
- Weakness
  - Donor may dictate project, interest in research and not infrastructure maintenance (e.g. Hospital)
  - Financial instability: Center lives from year to year
  - Fund-raising activity ongoing to obtain ~ $20 million

Sources of International Funding and Requirements

- Understanding the types of grants, the funding agency culture and their requirements is crucial
- Who is best suited to be PI (required set of skills to get the funding and agency culture)
- Trust is required
- For example, Fogarty has re-entry grants to help support foreign investigators re-establishing themselves at home
- NIH specifies who can be PI scientist can apply as PI (usually they can unless otherwise stated)
- Some US sources do not allow foreign scientists to be PI
Estimated U.S. investment in GH Research and Development in 2003

<table>
<thead>
<tr>
<th>SOURCES OF FUNDING GH R&amp;D</th>
<th>$ MILLIONS</th>
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<tbody>
<tr>
<td>RX industry</td>
<td>2929</td>
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<tr>
<td>Biotechnology (2001)</td>
<td>2600</td>
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<tr>
<td>NIH</td>
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<td>CDC</td>
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<td>USAID</td>
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<td>Department of State</td>
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<tr>
<td>Department of Defense</td>
<td>61</td>
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<tr>
<td>Foundations &amp; independent Institutions</td>
<td>505</td>
</tr>
<tr>
<td>TOTAL</td>
<td>9454</td>
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</tbody>
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Globalization and Paradigm Shift

- Need to move away from individual led projects to multidisciplinary, institutionally led programs for sustainability
- Now large-scale, multi-centre, team-led, thematic programs of research
- Collaborations between basic researchers, epidemiologists, statisticians, clinicians, nurses, pharmacists, social workers, ethicists, policy makers

Shifting Paradigm

- Funding patterns are changing
  - More emphasis to empower local researchers
  - Shift away from small scale funding done by one individual towards large-scale project performed by multi-disciplinary teams of specialists
  - Large-scale science requires much more coordination and some degree of centralized management

Sources of International Funding

- Gates Foundation [www.gatesfoundation.org](http://www.gatesfoundation.org)
  - This foundation provides funding for programs that increase access to innovations in education, technology, and global health. In the past, they have provided funds for TB prevention and drug development

- Wellcome Trust [http://www.wellcome.ac.uk/en/1/pra.html](http://www.wellcome.ac.uk/en/1/pra.html)
  - This trust offers grants for research in the following general areas: biomedical research, technology transfer, history of medicine research, research in biomedical ethics, and public engagement in science

Sources of International Funding

  - Provides information on funding, grant, contract, research, and training opportunities with links to DHHS agencies
Sources of International Funding

- NIH grants.nih.gov/grants/index.cfm
  Provides a variety of tools for finding information on funding opportunities in the biomedical sciences, including the NIH Guide for Grants and Contracts

NIH – Grant Awards, by Type

- Research Grant Programs (8 types)
- New Investigators Program (2 types)
- Multiple Principal Investigators (NEW in Feb 2007)
- Research Supplemental Programs (1 type)
- Ruth L. Kirschstein
  - National Research Service Awards (NRSA) (8 types)
  - Research Ethics and Training Grant Programs (2 types)
- NIH Career Development (K) Awards (15 types)
- Small Business Awards (1 type)
- Other Programs (8 types)

Sources of International Funding

- NIAID www.niaid.nih.gov/ncn
  NIAID-sponsored funding information
  Provides a "tool box" with instructions and advice for completing grant applications

- Research to the Presidential Vaccine Initiative-Overcoming the Tuberculosis Latency Challenge
  The purpose of this fund is to stimulate investigator-initiated research to elucidate the mechanisms underlying persistent, asymptomatic infection with *M. tuberculosis*.

NIH Research Training & Career Development Timetable

Sources of International Funding

- Fogarty: http://www.fogartyinternational.org/GRANTS/index.htm
  Only NIH institution that funds International Research specifically
  - ~ $50 million in grant awards
  - 1/3 Research, 2/3 Research Training
  - Awards range $10,000 – $1 million
  - Low and Middle Income Countries
  - Research Capacity Development and Equity

Research Training Program Characteristics

- Flexible
- Long-term commitment
- Built on research collaborations
- Re-entry support
- Response to local needs
- Empowerment
- Networking
The END

Thank you for your attention.