



International Research Agreements University Perspectives

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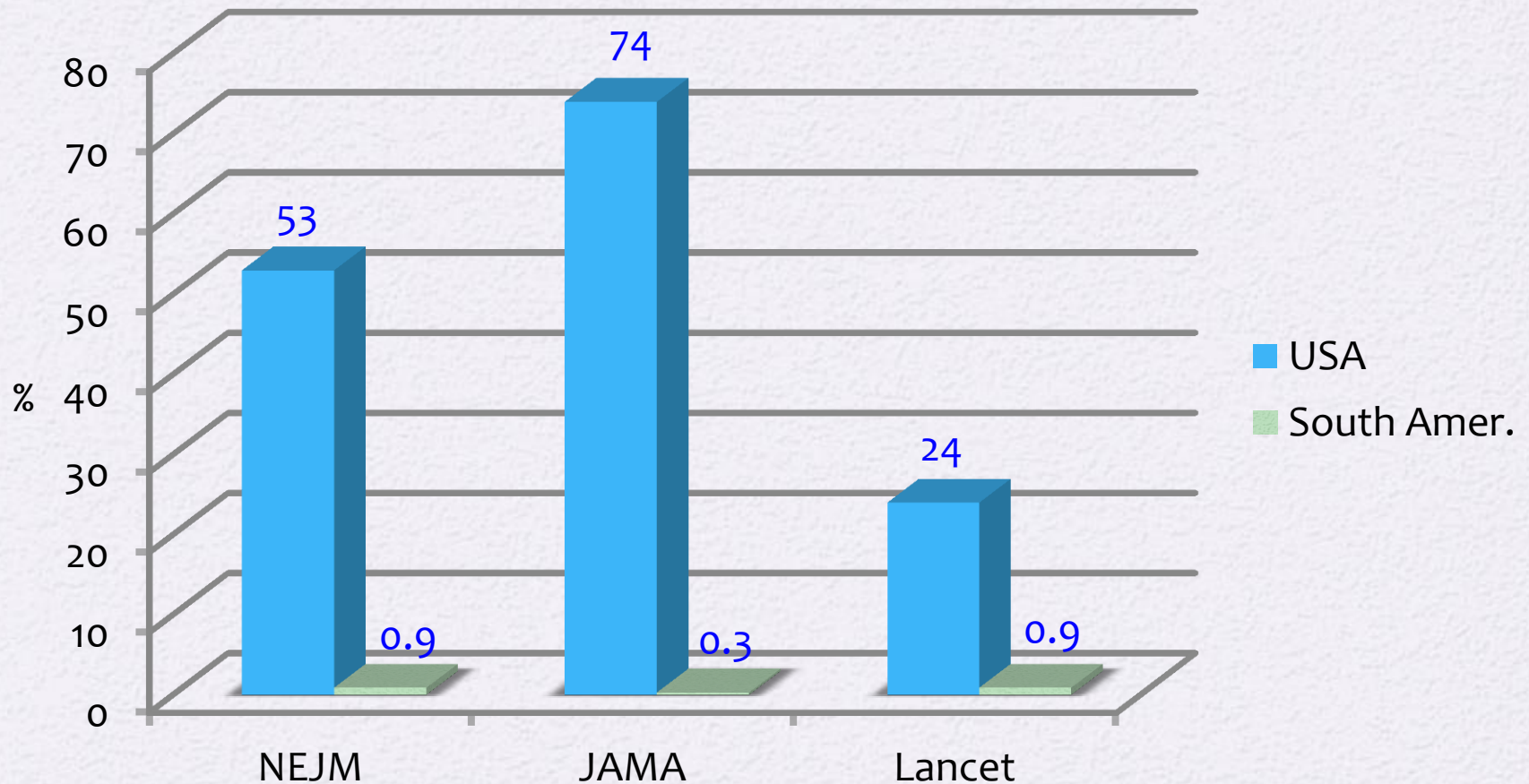
Research collaborations

- Laboratory research not involving human subjects
- Animal research
- Human research: basic, clinical, drug development, treatment, prevention

Unbalanced collaborations

- Large disparity in economic power, political influence and scientific expertise
- Weak regulatory framework
- More dependency on research support from the private sector

Regional origin of publications in three scientific journals - 2003-2010



Human research -Early period

- Research “collaboration” with developing countries usually aimed to address a US need
 - Studying diseases affecting productivity of US companies
 - Performing studies deemed too risky for US subjects
 - Taking advantage of lower costs
 - Circumventing US regulatory restrictions

Ethical vulnerabilities

- Lack of experienced, independent review boards
- Low-income populations, more susceptible to incentives to participate
- Assessment of risk biased by prevailing socioeconomic conditions
- Low literacy may prevent truly independent informed consent

The Cutler studies in Guatemala

1946 - 1952

- Healthy people were inoculated with syphilis
- Inoculated sex workers were forced to have sex with healthy people to study transmission
- Approved by the NIH, the Surgeon General, the Pan American Health Organization, and the Ministry of Health of Guatemala
- Details of the study kept secret from key personnel in Guatemala

BUENOS AIRES HERALD

Tuesday, January 3, 2012

GSK fined over vaccine trials; 14 babies reported dead

The charges included experimenting with human beings as well falsifying parental authorizations so babies could participate in the vaccine-trials conducted by the laboratory from 2007 to 2008.

THE NEW YORK TIMES

July 22, 2013

Glaxo Says Executives May Have Broken Chinese Law

By DAVID BARBOZA

SHANGHAI — The British pharmaceutical giant GlaxoSmithKline said Monday that some of its executives might have broken the law in China, the company's strongest statement yet on a bribery and corruption scandal that has engulfed its China operations.

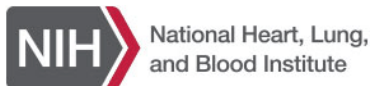
Executives at the British drug maker GlaxoSmithKline were warned nearly two years ago about critical problems with the way the company conducted research at its drug development center in China.

Principles of collaboration

- Topic of relevance for the local population
- Shared risk
- Clear regulatory framework
- Strong local ethical expertise
- Unbiased funding

Current approaches

- Research projects must include capacity building in research bioethics
- Research protocols approved by local, independent, internationally-registered internal review boards (IRB)
- The majority of research funds should be controlled by local institutions and PI's


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Tuesday, July 23, 2013

 Guatemala
NHLBI Office of Global Health

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GLOBAL ALLIANCE FOR CHRONIC DISEASES

NHLBI GLOBAL HEALTH PROGRAMS

Guatemala - Institute of Nutrition of Central America and Panama



Center of Excellence

Institute of Nutrition of Central America and Panama (INCAP)

 Guatemala City, Guatemala
 Principal Investigator: Manuel Ramirez-Zea, M.D., Ph.D.
[INCAP](#)

Center of Excellence Activity Sites

Mesoamerica and the Caribbean, which includes the following areas:

- Southern Mexico
- Central America (Guatemala, Belize, El Salvador, Honduras, Nicaragua, Costa Rica, Panama)
- Dominican Republic

Developed Country Partner

 Johns Hopkins University, Bloomberg School of Public Health, Baltimore, Maryland, USA
 Principal Investigator: Benjamin Caballero, M.D., Ph.D.

Background

In the Mesoamerican region, chronic noncommunicable diseases, particularly cardiovascular diseases (CVD), hold first place in mortality rates compared to other causes of death. CVD are the main cause of death in all countries, with the exception of Guatemala. However, when cancer and CVD are taken together, these two groups of diseases are the most prevalent causes of death in all countries, with rates higher than those found for communicable diseases and external causes. Belize, the Dominican Republic, Honduras, and Nicaragua have CVD mortality rates (adjusted by age and population size) equal to or greater than those reported in the United States.



Working Together



The NHLBI and UnitedHealth Chronic Disease Initiative are working together to establish a network of **11 Collaborating Centers of Excellence**.

News Releases

[National Heart, Lung and Blood Institute's Global Health Initiative: an Introductory Video](#)
[Global Heart: Special Issue on Indoor and Outdoor Air Pollution, and Cardiovascular Health, edited by Eser Tolunay and Arun Chockalingam of NHLBI](#)
[The Lancet Global Burden of Disease Study 2010](#)
[» World Alliance of Health Researchers Announces Priorities](#)
[» NHLBI Funds Centers of Excellence in Developing Countries and Collaborates with UnitedHealth's Chronic Disease Initiative.](#)
[» NHLBI Global Health Strategic Plan](#) (9 MB)

Promote Global Health

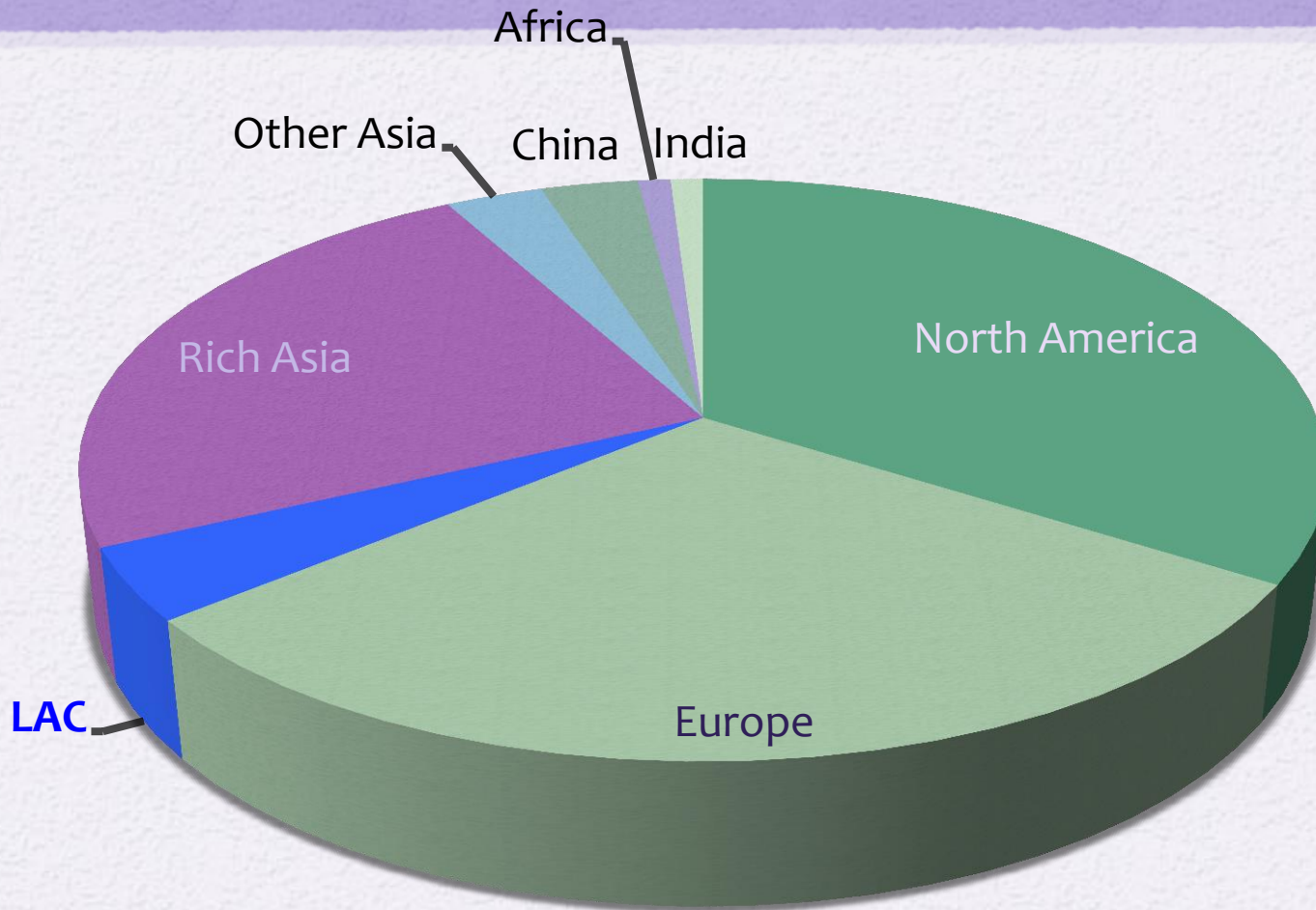
Low income vs. middle income countries

Country classification (World Bank)

GNI *per capita*

- Low income $\leq \$ 1,035$
- Middle income
 - *Lower middle* $\leq \$ 4,085$
 - *Upper middle* $\leq \$ 12,615$
- High income $>$

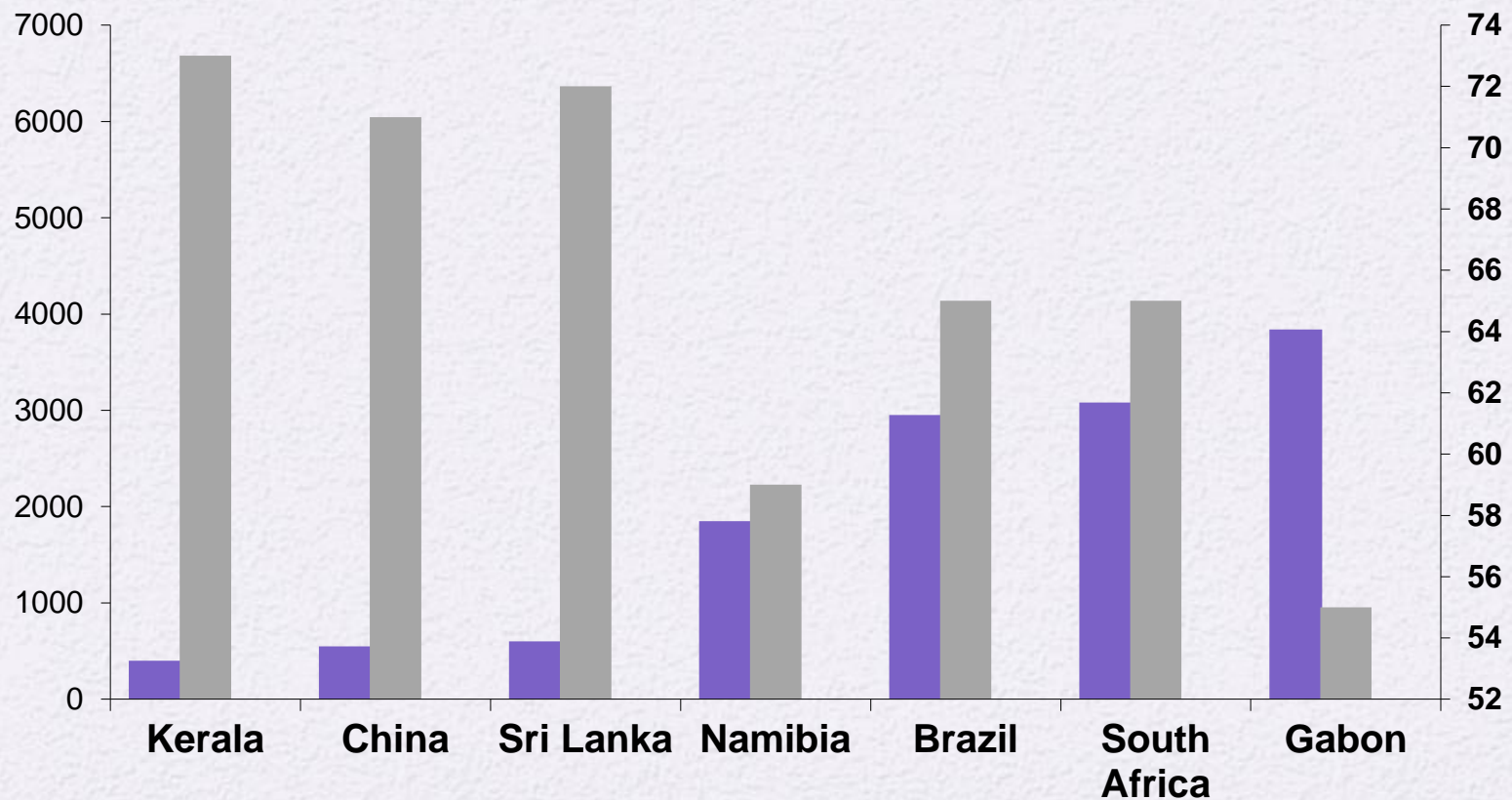
Wealth Share



GNP and life expectancy

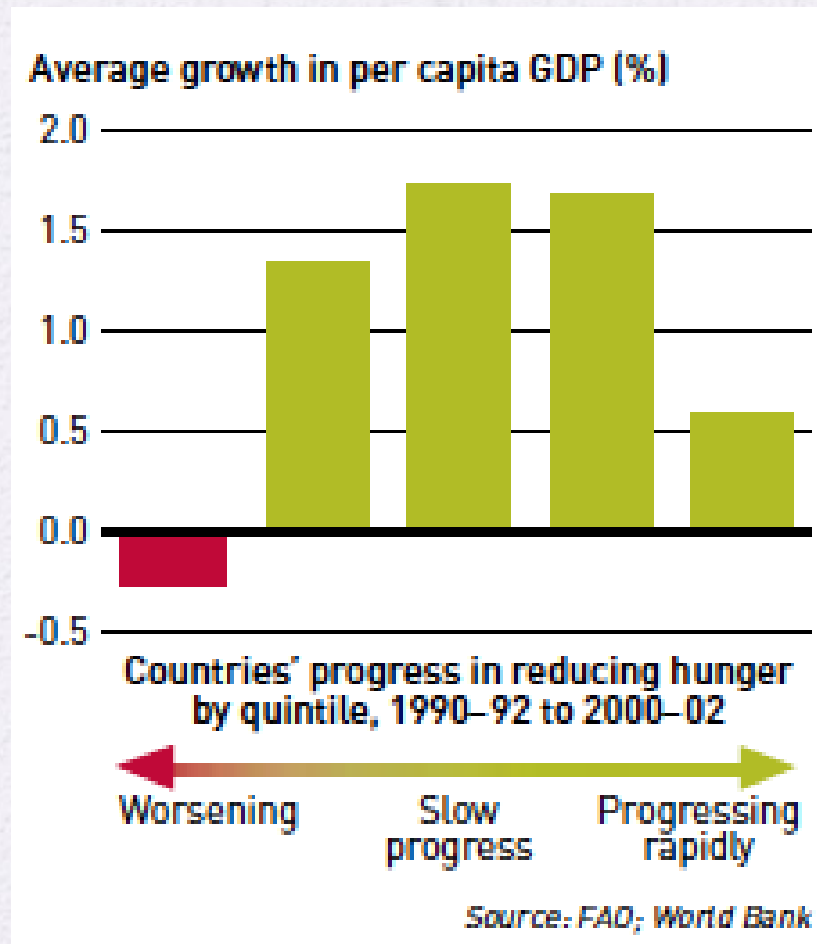
GNP per capita, USD

Life expectancy, yrs



A. Sen, Lancet 1999

GDP growth and progress in reducing hunger



Conditions for research collaboration

- Is there political/social support for science?
- Are there defined strategic goals for research?
- Is there a strong, reliable counterpart organization?
- Are basic accountability principles in place?
- Is there a potential for capacity building?

Conclusions

- Collaboration in biomedical research requires a solid, independent ethical framework of the developing country partner
- Equal and fair financial partnership
- Research goals aligned with recognized local priorities
- Bi-directional learning opportunities