

# HEALTH RELATED RESEARCH IN DEVELOPING COUNTRIES

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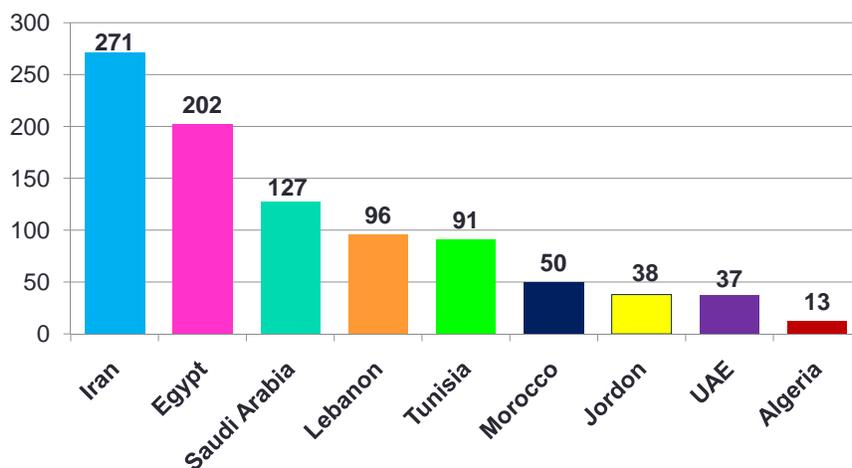
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## International Research

- Research carried out on populations in low and middle income countries and sponsored by foreign entities
- Number of clinical trials in developing countries has increased tremendously.
- Estimates exceed 40% of all current trials occurring globally.

## Number of Clinical Trials in MENA Region



Source: Advancing Clinical Research, in Turkey, Middle East & North Africa. 23-24 September, 2010

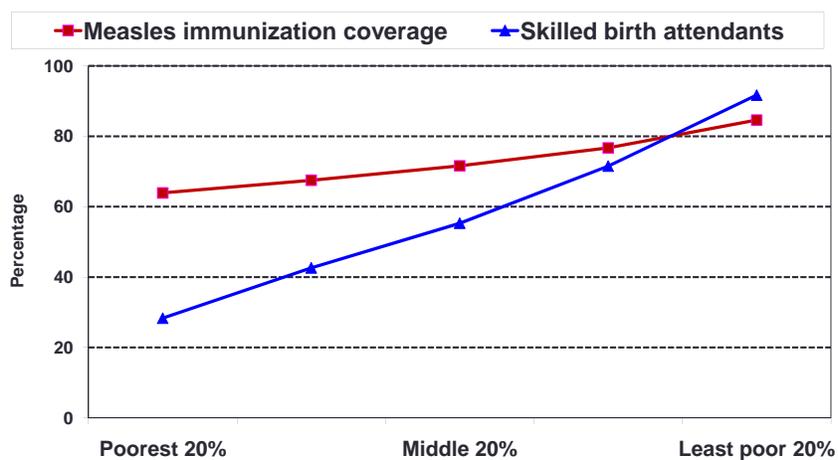
## Vulnerability of the World's Poorest People

- Over 1 billion people live on less than US\$1 per day
- High rates of illiteracy, especially among women
- Inadequate protection of human rights
- Inadequate experience with, or understanding of, scientific research

## Access to Health Care in developing countries

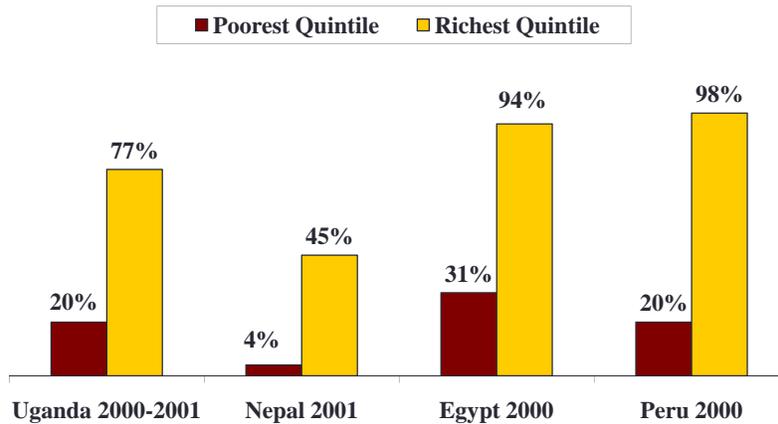
- Patients have limited or sometimes no access to health care
- WHO estimates that only 1% - 35% have access to preventive care.
- Millions of people die from preventable, curable diseases

## THE POOREST ARE LEAST LIKELY TO USE HEALTH CARE



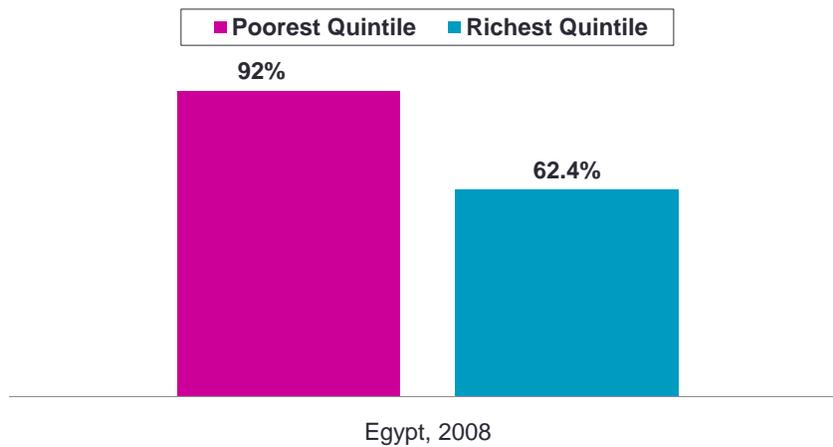
WHO Data for 47 developing countries

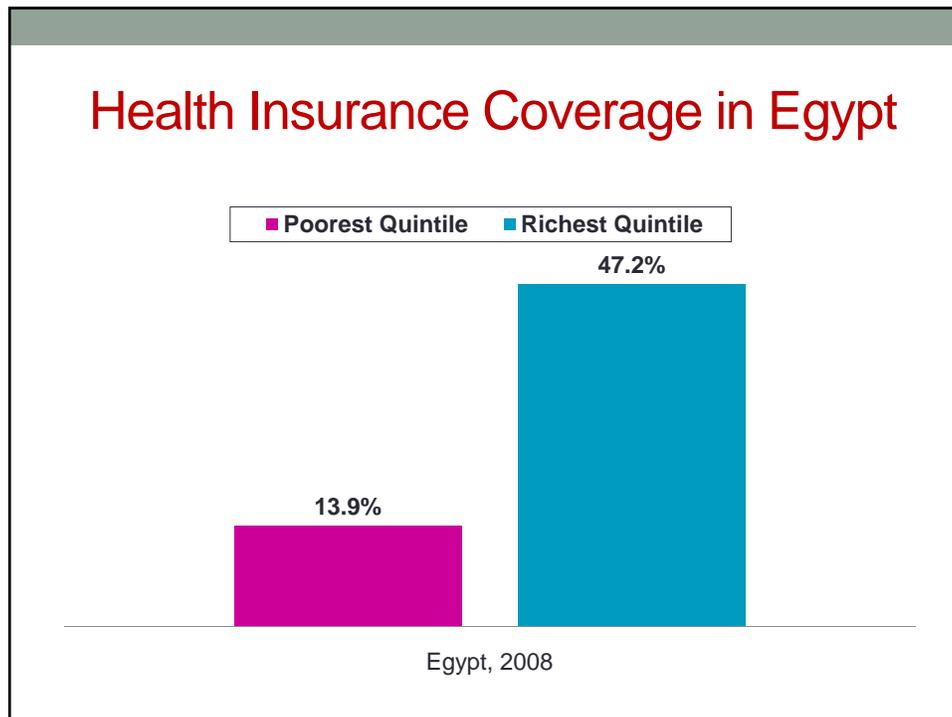
## Women Receiving Delivery Assistance



Source: D. Gwatkin et al., *Initial Country-Level Information About Socioeconomic Differences in Health, Nutrition, and Population*, Volumes I and II (November 2003).

## Females facing problems in accessing health care in Egypt





## Shifting Research To Developing Countries

- The United States accounts for ~ 4 % of the world's population versus 84% for Developing Countries
- About 90 % of resources are spent on the illnesses of the wealthiest countries, leaving only 10 % to care for 84 % of the global population

**[10/90 Gap]**

## Why Shift research to developing countries?

- Unique disease mapping with higher prevalence of certain diseases
  - Diabetes & Hypertension (25 - 27 % in Middle East)
  - Egypt has 8 -10 million hepatitis C cases (10% Prevalence)
  - HIV epidemic is sub-Saharan Africa
- Large patient populations
- Reduced timelines & costs
- Less stringent regulatory and ethical guidelines

## Declaration of Helsinki: Paragraph 17

Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is **responsive to the health needs and priorities** of this population or community and if there is a reasonable likelihood that this population or community stands to **benefit from the results** of the research.

How can research  
participants in  
developing countries  
benefit from Clinical  
Trials



### Declaration of Helsinki: Paragraph 33

At the conclusion of the study, **patients entered** into the **study** are **entitled** to be **informed** about the outcome of the study and to **share any benefits** that result from it, for example, **access to interventions identified as beneficial in the study** or to other appropriate care or benefits.

## CIOMS – Guideline 10

- In populations with limited resources, every effort must be made to ensure that:
- the **research is responsive to the health needs** and the **priorities** of the population or community in which it is to be carried out; and
- any intervention or product developed, or knowledge generated, **will be made reasonably available** for **the benefit** of that population or community.

## Fair Benefits ???

- Participants in poor countries often **join externally sponsored trials** in order to **access** basic health care and medication.
- Most participants **do not have a voice** in negotiating post-trial issues.

## Vulnerable International Populations

- **Distributive justice is violated**
- The local study populations will not significantly benefit from the research if the new therapies will not be affordable to them, although they are taking a higher proportion of the risk.

## Conclusion

- Over 1 billion people live in poverty and do not have access to basic health care
- In these populations the number of clinical trials conducted has increased
- How can these trials be conducted in an ethical manner without issues of exploitation?



**THANK YOU**