DEVELOPING WORLD RESEARCH AND PROTECTION OF HUMAN SUBJECTS

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GLOBAL BURDEN OF DISEASE

• Disease burden (DB) has become a privileged yardstick/indicator for health assessment, reform, policy development, planning, resource allocation, etc.
• Traditionally DB has been assessed using epidemiologic methods and statistics on morbidity and mortality.
• Recently more accurate methods, such as DALY’s (Disability Adjusted Life Years), have been used to quantify DB.
• Quantifies the impact of premature death and disability.
• Measures the outcome of specific health interventions.
• Such methods allow a more objective assessment and appreciation of the DB of any given part of the globe.
THE 10/90 GAP

- No matter the yardstick used, the global DB is heavily weighted against developing countries, particularly those of sub-Saharan Africa
- Here poverty and ill health form a vicious circle
- There is a glaring discrepancy between the availability of health research funding and the diseases responsible for the highest global DB
- This has been termed the “10/90 gap”: of an estimated US$ 73 billion invested (publicly and privately) in global health research annually, less than 10% goes to research into problems accounting for 90% of the global disease burden
- The Global Forum for Health Research has set itself the task of bridging this gap
AFRICA’S FORMIDABLE DISEASE BURDEN

- Communicable diseases, malnutrition, childhood diseases, maternal/perinatal problems, epidemics
- Despite significant improvement in child mortality, the rate is still 20x higher than in developed countries
- Despite significant reduction in maternal morbidity/mortality, 100x more African women die from pregnancy-related causes than in the developed world
- Despite improvement in life expectancy in the past two decades, it is still 10 years shorter than developing world average and 25 years shorter than developed world average
- Moreover, life expectancy is rapidly plummeting as a result of current epidemics, violence and other health/life threats
AFRICA: THE GLOBAL HQ OF THE HIV/AIDS PANDEMIC

- Sub-Saharan Africa has about 10% of the world’s population
- As of the end of 2003, about 53.7 million people living with HIV/AIDS worldwide
- 70% of these in sub-Saharan Africa alone
- Africa has the fastest rate of spread in the world
- Of the 4.8 million new cases of infection in 2003, 3 million were in sub-Saharan Africa
- Since outbreak of the epidemic, more than 17 million victims have died in Africa, 2.2 million in 2003 alone
WHY SITUATION IS PARTICULARLY CRITICAL

- High levels of generalized poverty
- Heavy burden of allied diseases: TB, Malaria, Typhoid, Meningitis, etc.
- Paucity of modern healthcare resources/facilities
- High levels of illiteracy and lack of awareness
- Difficulties in loco-motion and other forms of communication
- Lack of political will, political instability, conflicts, civil wars
- Resilient habits and practices harmful to health
- Hopelessness
TRIPPLE VULNERABILITY OF DEVELOPING WORLD POPULATIONS

• Vulnerability: “Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. …they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (Paragraph 1, Commentary on CIOMS 13)

• Vulnerability: Liability to be harmed, exploited, deceived or unfairly treated

• As members of economically disadvantaged groups (Helsinki #8, CIOMS 10 & 13)
• As members of medically disadvantaged groups – high burden of disease (Helsinki #8, CIOMS 13)
• As minors, increasingly used as research subjects (Helsinki #8, CIOMS 9 & 14)
• In Africa vulnerability equally applies to researchers, scientists, institutions, and even governments
ETHICAL IMPERATIVES OF RESEARCH, ANYWHERE, ANY TIME

• “…considerations related to the well-being of the human subject should take precedence over the interests of science and society (Helsinki 5)

• No harm (*primum non nocere*)
• No exploitation
• No deceit (Informed Consent)
• No cheating (justice and fairness)
CHARACTERISTICS OF INDUSTRIALIZED WORLD MEDICAL RESEARCH

Market-oriented
Profit-driven
Susceptibility to morally blind economic forces
High degree of ad hoc rationalizations and ethical ‘justifications’

Examples:
Definition of death and personhood debate directly related to need for non-therapeutic abortion and harvest of human spare parts from the ‘dead’
Placebo-control studies debate (Helsinki/CIOMS) directly related to need for HIV/AIDS vaccine research
CHALLENGES OF DEVELOPED WORLD
MEDICAL RESEARCH IN THE DEVELOPING WORLD

• Can commercial motives be combined with altruistic philanthropy?
• Can such research be non-exploitative?
• Can it avoid harming the vulnerable?
• Can it avoid applying double standards?
• Can it avoid undue-inducement?
• Can it apply the imperative of autonomy or respect for persons?
• Can it separate ethical imperatives from culture and ideology?
• Dilemma: to go or not to go?
AGE OF HEALTH RESEARCH STUDIES

• “As a recent study has shown …”
• Ethics Committees and Institutional Review Boards (IRBs) inundated
• Many of the proposals under review and much of ongoing research target or are in the “developing world”
• Africa seems to present the biggest and most attractive laboratory for these researches
• There seems to be a second scramble for Africa
• Any medical research in Africa, involving human beings faces very high ethical hurdles
WHY THIS NEW SCRAMBLE FOR AFRICA?

• Bridging the 10/90 gap as a matter of global rational self-interest (*Global Forum for Health Research*)?
• Altruism: Empathy, Sympathy and Philanthropy?
• Exploitability: abundant availability of diseases and patients, “resource poverty”, absence of constraining regulatory frameworks?
• All of the above?
CURRENT RATIONALIZATIONS FOR MEDICAL RESEARCH IN AFRICA

• Majority of diseases (epidemics) are occurring in Africa
• The devastating effects of these on health, security and on the social and economic fabric of life threaten the very existence of Africa
• Many of the existing medicines are either unavailable or unaffordable to people in Africa
• There is the need to research for affordable medicines and market-driven research needs special incentives to carry out such research
• The process of researching will contribute to capacity-building and infrastructure development
WHY DO RESEARCH SUBJECTS NEED PROTECTION?

• It is not easy not to take advantage of the weak, needy, poor, ignorant and vulnerable
• Past atrocities, harms and abuses
• Contemporary malpractices
• Ongoing problems
• Biomedical research has become big business
• Wherever big business driven by the profit motive, power and influence are at play, ethics, justice and fair play are likely to be swept under the carpet
NEED FOR CLEAR DISTINCTIONS AND EXPLANATIONS

• Treatment or research? Or treatment combined with research?

• Scientific knowledge or art of treatment and healing?

• Business/commerce or altruistic philanthropy? Or business/commerce combined with philanthropy?
DISTRIBUTIVE JUSTICE

- According to John Rawls (A Theory of Justice) “Justice is the first virtue of social institutions, as truth is of systems of thought”
- An untrue theory, no matter how attractive must be rejected; an unjust system or procedure, no matter how convenient or profitable must be reformed
- Society/community is a cooperative venture and distributive justice is concerned with the fair distribution of those goods, benefits, advantages, etc. resulting from collaborative ventures
- Medical research is a collaborative/cooperative venture that is becoming increasingly commercialized
- Morality/ethics includes but goes beyond justice
THE INDISPENSABLE NECESSARY PRECONDITIONS OF MEDICAL RESEARCH

- Good science/scientific design
- Adequate resources/funding
- Well-informed, free and willing subjects
- The role of the third person of the above trinity has been generally undermined and undervalued
Distributive Justice?

- What about a well-informed contract between:
  - Sponsor
  - Investigator
  - Subject
  - ???