

Ethical Considerations For Human Challenge Studies: The WHO perspective



Dr. Abha Saxena

Coordinator, Global Health Ethics

2nd Human Challenge Trials in Vaccine Development

IABS

28-30 September 2017

GLOBAL HEALTH ETHICS TEAM



Working in the WHO and Beyond

- Supporting ethics within WHO
 - Research Ethics Review Committee - ERC
 - Public Health Ethics Consultative Group
 - Incorporating ethics in technical guidelines
 - Staff capacity strengthening – workshops, e-training
- Health ethics across the globe
 - Developing normative guidance
 - Training tools
 - Capacity strengthening workshops



Global Health Ethics Unit



Dedicated to the Ethics of
Public Health and Research

Why WHO ?

- Trusted, neutral partner
- Convening Power
- Developing countries look to WHO to provide advice, especially on contentious issues



Casebook on Ethical Issues in International Health Research

Editors:
Richard Cash
Daniel Wikler
Abha Saxena
Alexander Capron



Standards and Operational Guidance for Ethics of Health-Related Research with Human Participants



Orientations sur l'éthique en matière de prévention, de soins et de lutte contre la tuberculose



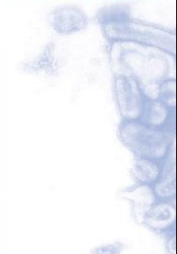
Ethical issues in Patient Safety Research

Interpreting existing guidance



Addressing ethical issues in pandemic influenza

DISCUSSION PAPERS



Guidance For Managing Ethical Issues In Infectious Disease Outbreaks



science research: opportunities and risks in public health

Addressing the issues

Research Ethics in International Epidemic Response

WHO Technical Consultation
Geneva, Switzerland
10–11 June 2009
MEETING REPORT



Consultation on ethics and equitable access to treatment and care for HIV/AIDS



Summary of issues and discussion
26–27 January 2004
Geneva
World Health Organization and
Joint United Nations Programme on HIV/AIDS



WORLD HEALTH ORGANIZATION

WHO/STP/ERT/7-2003.1

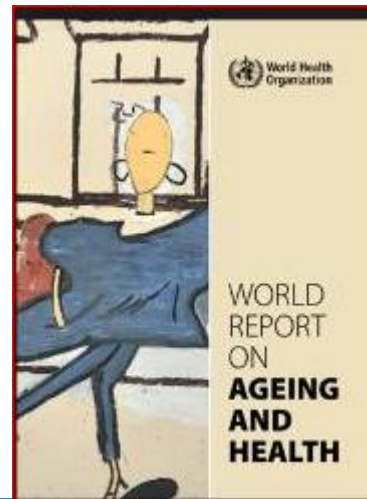
Ethics, access and safety in tissue and organ transplantation: Issues of global concern
Madrid, Spain, 6-9 October 2003

Report



Current Activities

- Vector Borne Diseases and ethical implications and treatment
- Healthy Ageing
- Antimicrobial Resistance



ANTIMICROBIAL RESISTANCE
Global Report on surveillance 2014

What you need to know
WHO's first global report on antimicrobial resistance, with a focus on antibiotic resistance, reveals that it is no longer a prediction for the future. Antibiotic resistance - when bacteria change and antibiotics fail - is happening **right now**, across the world

CC(=O)N[C@@H]1[C@H](NC(=O)O)S[C@@H]1



Supported by

- Global network of WHO Collaborating Centres
- Regional focal points,
- Interns

General email:

ct_ethics@who.int

Ethical Considerations For Human Challenge Studies: The WHO perspective

PUBLIC HEALTH ETHICS VOLUME 9 • NUMBER 1 • 2016 • 92-103

92

Ethical Criteria for Human Challenge Studies in Infectious Diseases

Ben Bamberg*, Monash University
Michael Selgelid, Monash University
Charles Weijer, Western University
Julian Savulescu, University of Oxford
Andrew J. Pollard, University of Oxford



Ethical Framework

- Risks (and benefits)
- Social Value
- Compensation for research related injury
- Vulnerable populations
- Right to withdraw
- Community Engagement



The WHO perspective

- Priority Setting
- Conditions to be satisfied for CHIM studies
- Trust Building
- Benefit Sharing
- Capacity Strengthening



Priority setting

- At least 14 pathogens for which discussions on CHIMs is taking place
- Criteria should be established for prioritising endemic pathogens in developing countries for the establishment of human challenge studies for elucidating the pathogenesis or for development of vaccines
 - Norovirus or shigellosis, or salmonella?
 - Intestinal parasites?
 - Zika?
 - All?
- Criteria for defining the problem statements



Conditions to be satisfied before undertaking Human Challenge studies

- Establishing risk criteria?
 - Would I do this on my blood relatives?
 - Risk of harm is reversible, non fatal, treatable
 - An upper limit of risk?

Furthermore, risk comparisons must not be made to activities that pose unacceptable risks themselves, or in which people choose to participate because of the associated benefits (some sporting activities, for example, are thrilling precisely because they involve an elevated risk of harm).

- Availability of ‘clean’ knowledgeKnowledge for the sake of knowledge – “you can do fantastic immunology...”?

Building and Maintaining Trust

- Increasing accountability
 - global database/registry of all CHIM studies
 - Global registry of all possible adverse events?
- What do we know about experiences of volunteers who have participated in human challenging studies conducted in developing countries?
- How are CHIM studies viewed by the public in countries in which they are undertaken? What is being done to understand the views of the populations?
- What is being done to increase understanding of the popular media for these studies?



Benefit sharing (CIOMS Guideline 2)

- Research conducted in low resource settings **must**
 - ensure that the research is responsive to the health needs or priorities of the communities or populations where the research will be conducted.
 - make every effort to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out,
 - assist in building local research capacity
 - consult with and engage communities in making plans for any intervention or product developed available, including the responsibilities of all relevant stakeholders.

This applies especially to CHIM studies

Role of Local and national ethics committees

- “.... Risks must be analysed by ethics committees”
- This is a complicated area – ethics committees – even in developed countries may not be best placed to evaluate the risk benefit ratio - requires a very good understanding of the science
 - Independent scientific review coordinated by the ethics committees
 - Advisory (global) ethics committee whose expertise could be tapped into
- Role of National Bioethics Committees – could contribute to building trust

Capacity Strengthening

- For research ethics Committees, and regulators.
- For public and the media
- Researchers and Research centres from developing countries
 - Controlled human infection model (CHIM) studies have pivotal importance in vaccine development, being useful for proof of concept, pathogenesis, down-selection and immunogenicity studies. Few have been carried out in low and middle income countries (LMIC), which is where the greatest burden of vaccine preventable illness is found
 - at the next IABS conference, I look forward to hearing more from investigators from developing countries leading research in their institutions.

