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Section C: History of Research Ethics in South Asia

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Objectives

- Describe the historical context of development of research ethics in (South) Asia with a focus on India
- Discuss contemporary issues in the conduct of research in humans in the region

Ethics in Traditional Medicine

- Prime concern—safety and best interest of patients
- Cost-effective treatment to the poor
- No drastic/costly measure for the incurable
- Maintain confidentiality
- Refrain from unsavory financial deals
- Refrain from advertising
- Professionalism with patients and colleagues

Post-independence

- Push for enhancing science and technology capacity
- Setting up of research institutes through the ICMR, Department of Science and Technology, and Department of Biotechnology
- Research with policy implications carried out, e.g., development of Directly Observed Treatment Strategy (DOTS) for TB at the National Tuberculosis Institute

Research Controversies: India

- Trials on cervical dysplasia in Indian women in the 1970s and 1980s
- 1990s: Use of antimalarial quinacrine as a terminal contraceptive in West Bengal
- 1999: Trial at Regional Cancer Centre in Trivandrum on patients without DCGI clearance and ethics committee clearance

Research Controversies: India

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- 1999: Trial at Regional Cancer Centre in Trivandrum on patients without DCGI clearance and ethics committee clearance
- Trials in women with injectable contraceptive Net-En with questionable consent
- 2003-04: Letrozole (anti-cancer drug) promoted by a pharmaceutical company surreptitiously as a fertility enhancing drug without conducting proper research
- Placebo-controlled trials in psychiatry, especially in patients with serious psychiatric conditions

Ethics Guidelines: India

- 1970: Central Council of Indian Medicine Act
- 1980: ICMR Policy Statement—first official guidelines for establishment of ethics committees in all medical colleges and research centers
- 2000: Ethical Guidelines for Biomedical Research on Human Subjects (revised 2006)
- 2000: Ethical Guidelines for Social Science Research in Health (non-government)
- 2001: Indian GCP Guidelines
- 2002: Medical Council of India Code of Medical Ethics
- 2007: Stem Cell Research Guidelines (with Department of Biotechnology)

Acts Governing Drugs and Cosmetics in India

- Acts and rules which govern the manufacture, sale, import, export, and clinical research of drugs and cosmetics in India
 - The Drugs and Cosmetics Act, 1940
 - The Pharmacy Act, 1948
 - The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
 - The Narcotic Drugs and Psychotropic Substances Act, 1985
 - The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
 - The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)

Role of NGOs and Activists

- Raising questions and concerns around medical practice and also research
 - MTP Act
 - PCPNDT Act
 - Critique of current Assisted Reproductive Technologies (Regulation) Bill and Rules 2008
 - Need for stricter regulation of research in the country

Institutional Level

- As institutions become more autonomous, conflicts of interest arise because of funding
- Issues around responsible conduct of research: authorship
 - “Polyauthoritis giftosa”
 - Plagiarism

Stem Cell Research and Therapy

- Clinics offering “magic” cures, conducting research in stem cell therapy raising difficult questions
- Requires caution given possibility of risk associated with these therapies

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PLOS MEDICINE

Donor-Derived Brain Tumor Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient

February 2009 | Volume 6 | Issue 2 | e1000029

Hwang Case: South Korea

- Falsifying research results—faked stem cell lines
- Coercion of juniors in the lab
- Submitting false findings to journals

MINISTRY OF HEALTH N.O.C. NO. F.12-9/2005-WHO

STEM CELL THERAPY

STEM CELL THERAPY TO TREAT THALASSAEMIA AND OTHER DISEASES
AS INAUGURATED BY PRESIDENT GENERAL PERVEZ MUSHARRAF
ON JULY 12, 2005

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INVENTED BY DR. ILHAM ABULJADAYEL

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Sri Lanka

- Controversy around research carried out post-tsunami in those affected and vulnerable
- Ethics of post-disaster research
- Sumathipala A, Sirribaddana S. Research and clinical ethics after the tsunami: Sri Lanka. *Lancet* 2005;366:1418-1420

Current Challenges

- Growing amount of research in sciences and social sciences
- Outsourced clinical trials
- Research in new frontiers of medicine, like regenerative medicine and nanotechnology
- Regulatory oversight needs to be more robust
- Need for training in research and for embedding ethics in research

Outsourced Clinical Trials

- Linked to cost cutting by global big pharma
- Mushrooming of CROs in the country
- Ineffective regulation and poorly staffed drug controller's office
- Pro-industry steps by government
- Ethics committees exist, but often there is no training and no registration or accreditation process
- Commercial or for-profit ethics committees coming up

Need for Trainings in Research Ethics

- Workshops and trainings being conducted in various parts of the country
- ICMR Fogarty grant for long-term bioethics training
- Need for more contextual research in the area
- Discussions happening through forums such as the *Indian Journal of Medical Ethics* (www.ijme.in)