

**Ethical, Legal And Social Implications
(ELSI) Of Biomedical Innovations For
Human Enhancement In Bangladesh
A Developing Country Of
South-East-Asia**

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Introduction:

Bangladesh is one of the world's most densely populated countries, with its around 160 million people overcrowded into a delta of rivers that empties into the Bay of Bengal. The country is bordered by the Bay of Bengal in the south, Myanmar in the south-east and India to the east, north and west. Ethical issues in research involving human participants are handled by a national committee. However, ethics review system in the country warrants substantial strengthening. The legal system practiced in the country is inherited from the British as the British has ruled the sub continent (India, Bangladesh, Pakistan & neighboring countries) for around 200 years. Many of the laws are very old, needs upgrading and ethical guidelines of the country for research involving humans though exist but not enacted as in many developing countries. Social system is characterized by extreme differences between rich & poor and the difference has an increasing trend with time. Islam is the largest religion of Bangladesh; Muslims constitute 90 % of the population, followed by Hindus, Buddhists, Christians and other religions. Religion plays pivotal role in availing opportunities for treatment as well as human enhancement. Biomedical innovations originated in the country are rare but innovations facilitating human enhancement are heavily imported to the country from

abroad. As a result issues related to biomedical innovations for human enhancement is very much relevant for this resource poor country of South-East Asia.

Enhancement and Biomedical Innovation:

Enhancement which is an indispensable part of human expectation may be defined as heightening, increasing & improving in value, quality, desirability or attractiveness. Enhancement broadly means to improve human form or functioning beyond what is necessary to restore or sustain health. However, sharp demarcation between treatment & enhancement is often tough.

The focus of the paper will be on enhancement ethics of innovations that make biological changes in human bodies and brains, using pharmaceutical, surgical, or genetic techniques.

Broad Aspects of ELSI:

The very basic dilemma of ethics is the lack of equal opportunity to use available biomedical innovations amongst the Bangladeshi people due to high cost. Biomedical innovations are mostly used by rich people, depriving the underprivileged people who extremely need enhancement. This creates a situation for widening the gap between rich and poor and in the long run develops a situation for exploitation of the poor by the rich.

Specific Aspects of ELSI:

Though enormous situations are in existence in Bangladesh raising ethical, legal & social issues, the following areas deserve discussion:

Assisted Reproductive Technology:

During the recent years the number of institutions mostly private engaged in Assisted Reproductive Technology has increased manifold in Bangladesh. But the technology is not affordable for majority of the prospective people due to high cost of the procedure. The religious factor is another major obstacle as use of sperm or ovum of a person other than the spouse is strictly prohibited, which strongly discourages establishment of sperm or ovum bank in the country. In absence of strict supervision & monitoring of the functioning of these ART clinics, ethical principles are often violated; commercial nature of many of the ART Clinics raises legal and social issues.

Test Tube Babies:

The practice is lawful in Bangladesh if it only involves a married couple. This practice is unlawful if it involves an alien party, whether in the form of semen, an ovum, an embryo, or a womb. That is the reason it is not widely practiced. And the benefit of this innovation cannot be widely shared by the people due to socio-cultural reasons.

Fetal Sex Determination:

Socio-cultural context of the population of the country encourages preference of male child and still women are blamed for giving birth to a female child which may end with a second marriage of the husband (Islam allows more than one wife if there is a substantial reason for that) for the hunt of male child. The negative impact of the fetal sex determination results in misbalance of proportion of

male & female population in the society. This has ethical and social implications. Abortion is illegal in the country due to Islamic laws. Two statements from Al Quran & Islamic Organization related to abortion are mentioned below:

“Kill not our children for fear of want. We shall provide sustenance for them as well as for you. Verily the killing of them is a great sin” - Al Quran, Surah No.17, Ayat No.31

“An embryo is a living organism from the moment of conception, and its life is to be respected in all its stages especially after spirit is breathed in. Aggression against it in the form of abortion is unlawful except in case of maximum necessity.” -Islamic Organization of Medical Sciences (Kuwait, May, 1983).

Under these circumstances the women who are bound to get rid of the fetus (female) adopts unfair means for abortion, which results in complications even leading to death. Also this is a violation of law. In Bangladesh menstrual regulation is allowed if there is a medical indication and according to the Islamic law abortion of a severely affected fetus (within 120 days of pregnancy) may be permitted.

Human Genetics:

Islam welcomes use of genetic engineering, gene therapy and other opportunities aimed at treatment & human enhancement. However, such use has to be within the boundaries of principles in Islamic Jurisprudence (Majlish-e-Ulama e Islam, Singapore, November, 2001). Islamic Jurisprudence prohibits certain practices like

use of donor sperm, ova and uterus. Neonatal diagnosis and genetic counseling is acceptable. However prenatal diagnosis is considered to be unacceptable according to Islamic philosophy.

Use of Stem Cell:

Stem cells are characterized by ability to renew themselves through mitotic cell division and differentiating into a diverse range of specialized cell type. Several Islamic scholars have pointed out that cloning embryos for therapeutic uses would also be permitted.

Under most interpretations of Islamic law, the embryo is not considered a person and the use of it for stem cell research does not violate Islamic law. Production of tissues or organs by cloning for transplantation purposes may be allowed. However, creation of fetus from the genome of only one individual is prohibited in Islamic Shariah.

Islamic law also prohibits surrogate parenting or adoption. Embryos cannot be used by anyone except couple who created them. So it is a societal obligation to perform research on these extra embryos instead of discarding or killing them.

Organ (Kidney) Transplantation:

According to a law regarding tissue transplantation practiced in the country only blood connected relatives are allowed to donate kidney. But due to poor socio-economic condition, underprivileged people

used to sale one of their kidneys. This raises ethical (harm to donor, business with human organs), legal (falsification in identification of blood relation) & social (exploitation of the poor by the rich) concerns.

Clinical Trial:

It is important to consider the issues of clinical trial to establish effectiveness of new drugs & vaccines, which are subsequently used for human enhancement. Clinical trials increasingly occur on a global scale as industry and government sponsors in wealthy countries move trials to less wealthy countries. Many of these trials are being conducted in developing countries. An important force that is moving clinical trials to developing countries is the increasingly bureaucratic and expensive regulating environment in many wealthy countries. South-East Asia due to its large population (Bangladesh: 153.5 millions, India: 1148.0 millions, Indonesia: 237.5 millions) is a favorable site for clinical trials. Quality of Clinical Trial depends on the optimum decision making by Sponsors, Ethics Committee, Regulators, Investigators, Healthcare Professionals and Study Participants.

In recent years, there has been substantial debate about the ethics of research in developing countries. The main concern fuelling the debate about the ethics of international health research has been the potential for exploitation of research subjects in developing countries by researchers from developed countries who may be motivated by interests that supersede concern for the well being of the research subjects. An ethical framework for multinational research should minimize the possibilities of exploitation. The weakness of review system may raise question on protection of human participants involved in the clinical trial.

In Bangladesh a number of clinical trials are being conducted mostly under international collaboration but due to weakness of review mechanism, in many cases safeguarding the interest of the research participants is under question.

Clinical Trial Registry: The International Committee of Medical Journal Editors (ICMJE) initiated a policy in 2005 requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrollment. The World Health Organization (WHO) has established International Clinical Trial Registry Platform (ICTRP). The WHO's global efforts toward comprehensive trials registration and the ICMJE's requirements for registration aim to increase public trust in medical science.

No clinical registry has yet been established in Bangladesh. Though several clinical trials are under implementation in the country, which are being conducted in collaboration with international institutions. It is worth mentioning that in South East Asia Region Sri Lanka, India & Thailand have established Clinical Trial Registry (CTR) and Indonesia is trying to establish CTR. In order to improve the quality of clinical trials & facilitate dissemination of information on the clinical trials among the relevant parties, it may be necessary to establish CTR in Bangladesh. More stringent regulatory mechanism is required to minimize number of studies that are conducted with invalid informed consent, undue inducement and are raising several ethical concerns & social implications.

Use of Vaccines:

In Bangladesh current priorities include vaccines to control diarrheal diseases, including oral cholera

vaccines and rotavirus vaccine, and those for prevention of respiratory infections, the biggest global killer of children. Bangladesh has been strong supporter of the WHO's BRaVe (Battle Against Respiratory Viruses) initiative. The Government of Bangladesh has a program called EPI (Extended Program of Immunization) which provides free vaccination for mothers & children and number of this free vaccination is limited. There are other vaccines available in the private sector for preventing several other diseases. But due to the high cost of these vaccines only a segment of the total population are able to enjoy the benefit of these vaccines.

Transfer of Biological Materials:

In absence of modern laboratory facilities biological materials of Bangladeshi populations are being transferred to different countries for diagnosis as well as for research purpose. In the era of genomic research it raises lots of ethical, legal & social issues. In absence of material transfer agreement with the parties transferring biological materials, population as a whole remains vulnerable to certain risks.

Technology Transfer:

The legislations of drugs [according to the Drugs (Control) Ordinance, 1982] in Bangladesh provided impede for technology transfer related to drugs and pharmaceuticals. Under that regulation no foreign company could transfer technology to a local manufacture unless they have their own set up in Bangladesh. However, after the amendments of the Drugs (Control) Ordinance in 2006 there is no restriction to produce any drug under mutual agreement with any pharma companies of the world. Some of the local companies are now producing few high-tech products under license from foreign companies, which in turn benefiting the users.

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This has increased the opportunity of using high-tech products for human enhancement. Although a privileged segment can only afford this.

National Innovation System in Bangladesh:

National Innovation System in Bangladesh consist of several laws guiding innovation and institutions who are contributing toward biomedical innovations in the country:

Laws:

Patent and Designs Act, 1911; Patent and Designs Rules, 1933; Secret Patent Rules, 1933; Copyright Law, 2000 (amended in 2005); Trademarks Ordinance, 2008; Revised Trademarks Rules, 1963 etc.

Institutions:

Institutions Providing S&T and Innovation: Bangladesh Academy of Sciences, Bangladesh Association for Advancement of Science, Bangladesh Association of Scientists and Scientific Professions, Mono-disciplinary Scientific Societies, Science Clubs etc.

In addition there are

Scientific Professional Societies & Think Tanks.

New Challenges:

Advances in human enhancement encounters policymakers with new challenges. Two of the interrelated issues relate to access to new technologies and the appropriate role of government in their oversight. To understand and define the role of law makers in regulating this technology is critical. If the process for developing and using regenerated tissues and organs is not properly regulated, the integrity and safety of the biological products created by these enhancement technologies could be compromised and endanger humans exposed to them.

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