

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

**1. How would you define an ‘emerging technology’ and an emerging biotechnology’**

If science is knowledge then technology is skill to use that knowledge. A technology is said to be emerging when it is new and hitherto has not been in use in society. A technology is emerging when it utilizes an energy source hitherto not tapped eg. Microwave radiation

I would categorize technology into four groups (i) Computing technology (ii) Communication technology (iii) Assisted Reproductive Technology (ART) and (iv) Agro food technology

*All these three categories ultimately, directly or indirectly, in one way or other affect human life and human health. Hence they have a biotechnological character to it whether they use a biological organism or its parts.*

**2. Do you think that there are there features that are essential or common to emerging biotechnologies?**

What is common among these technologies is that they use natural components that have not been in use so far. For instance micro wave that are not so common in the visible range. In food technology we used pesticides like DDT which is not found naturally in Nature. Currently we use methyl iodide which is deadlier than DDT . These are two such good examples. In reproductive technology the use of IVF is yet another technology that has immense potential to tide over infertility. These are not natural procedures but are artificial since they utilize human expertise. All these technologies are good in themselves but they are not good enough for human happiness. The common denominator seems to be ‘market value’ and ill health to humans and human society.

**3. What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?**

(a) I think that ART and IVF are the most important technologies that have ELSI implications because they change social and family values hitherto considered pristine and sacred. Before replacing the ‘established values’ in human family institution, with the new and unknown values the credibility of the new values needs to be first established. It is not wise to destabilize established values with unreliable

values. How would these new values be assessed? It is impossible to do this experiment. It is like the “grand father fallacy” in cosmology. Most of the emerging new values create a conflict of interests with the established values. For instance, the desire to live long using health care technologies conflicts with an ‘empty life’ with enhancement in average life expectancy. Likewise the need to provide food to hungry mouth with genetically modified food crops exhibits a conflict of interest with the desire to be fertile in biological life. The burden of infertility due to the use of fertilizers and inbuilt generation (in GM crops) of phyto-hormones like environmental mimics of the female reproductive hormone estrogen stands in contradiction with the burden of surrogacy in pregnancy. These impacts due to reproductive technologies are difficult to reverse. They will create a new ecological balance.

- b) Stem cell research has prospects but the promises that are projected are not realistic and it is a blatant lie
- c) Assisted Reproductive Technology has become a money spinning industry and some doctors (as has been reported in Brazil) do not have proper register of gamete transfer. Their high success rate has been attributed to indiscriminate gamete utilization.
- d. Assisted Suicide Technology – the painful life of elderly who have found no meaning in life and thus would like to express their option for the FEN (Final Exit Network) as quickly possible. This is one side of the coin. The other side is to bring these established organizations under strict policing and regulations i.e. to regulate these established organizations to maintain good record of their clients,
- e. Micro chip implantation and synthetic biology. The promise offer is too high to be a realistic endeavor and human enhancement.
- f. Genomic medicine can it deliver what it promises without much risks and side effects?

4. Are there examples where social, cultural and geographical factors have influence the development of emerging biotechnologies (either in the past or currently)?

Parents are anxious that their children should be champions in sports. American companies are exploiting such a desire. American company like American International Biotechnology Services is selling DNA kits to parents so that they can maximize sports performance with least efforts and with minimum risks. But there is no scientific evidence to prove that genes have any influence on athletic abilities. Such commercial enterprises will raise ethical, legal and social problems.

5. Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?

India is a conservative society as far as reproductive practices are concerned. And child bearing has a social status. Infertility is creeping in. There is a need for ART which is now globalized and hence there is no geographical distinction.

**An extract from my paper - paper copy attached**

A commercial surrogate mother agrees with the commissioning couple or a single parent to rent her womb. For bearing the burden of pregnancy she is paid a fee of around \$25,000 to \$30,000, which is just a third of what it will cost in USA. The Law Commission of India studied the prospects of Indian Market for surrogacy and came up with its recommendations. The low cost in India “has made India a favorable destination for foreign couples who look for a cost-effective treatment for infertility. As a result, a whole branch of medical tourism has flourished on the surrogate practice. In the open market Indian ART **industry** is now a 25,000 crore rupee pot of gold. Anand, a small town in Gujarat, has acquired a distinct reputation as a place for outsourcing commercial surrogacy. It seems that wombs in India are on rent which translates into babies for foreigners and dollars for Indian surrogate mothers” (GIO, 2009).

Hence the Indian environment is for commercial surrogacy and letting the wombs to have babies for infertile men all over the world has been considered as a prospective “pot of Gold”. While a foreigner can have a baby, the Indian surrogate mothers will earn in dollars. India cultural milieu is conservative and it remains to be seen how legislative measures will keep social and family values intact. India has splendid legal environment in terms of laws and it is a different story when it comes to the question of implementation. It may be recalled that Government had to cancel the license of thirteen hospitals for engaging in illegal activities in organ (kidney) transplantation.

**6. Are there examples where internationalization or globalization of research, markets and regulations have influenced the development of emerging biotechnologies?**

When we talk about globalization of research, markets and regulation, the area that comes to my mind immediately is the IVF market. Baby making has become an international market.

**7. How have political traditions and conditions (eg. War) influenced the emergence of biotechnologies ?**

I really do not have an answer.

**8. Are there ethical or policy issues that are common to most or many emerging biotechnologies?**

The commonality among the emerging biotechnology whether it is agro food technology or any other technology is that they target the younger and upcoming future generations

i.e. children. The other section of the society that is adversely affected is the elderly population. They are terrorized with the fear of euthanasia

#### Example 1

Enhanced food production through technology has become a cause for ill health concerns. When a child eats a pineapple or strawberries that are grown with a rich supply of fertilizers then it results in ill health. The skin is affected and results in latex allergy. The changes in skin condition are similar to eczema. Further it also results in hypersensitivity which includes conditions such as hyperactivity, fidgeting, inattention and impulsivity. These common disorders go by the term Attention Deficit Hyperactivity Disorder (ADHD). About 10% of the American children suffer from ADHD. According to Dr. Pelsser, 64% of children diagnosed with ADHD are actually experiencing a hypersensitivity to pesticide contaminated food (Vegsource, 2011).

#### Example 2

Economic achievement in food production (strawberries) is not without a hidden health cost. Theodore A. Slotkin, is the professor of pharmacology and cancer biology at Duke University Medical Center. He has expressed a deep concern by mentioning: "I'm not in blanket opposition to the use of pesticides, but methyl iodide alarms me. When we come across a compound that is known to be neurotoxic, as well as developmentally toxic and an endocrine disruptor, it would seem prudent to err on the side of caution, demanding that the appropriate scientific testing be done on animals instead of going ahead and putting it into use, in which case the test animals will be the children of the state of California." If children are used as guinea pigs in an attempt to boost the profits then it is a competing but conflict of interests.

#### Example 3

In the year 1990s Jack Kevorkian, the Michigan doctor, assisted in the deaths of 130 terminally ill people. He was Dr. Death. But the report also revealed the existence of a well organized group which called itself as Final Exit. Dr. Jack died on June 3, 2011. The 83 years old, Dr. Lawrence Egbert, as the Medical Director of the Final Exit Network (2011), has access to the applications filed by candidates who want to commit suicide. His conscience as a minister at the University Unitarian Chapel and as a lecturer at the John Hopkins Medical School did not deter him from assisting about 300 Americans to find the final exit into eternity (Cook, 2011). He is the modern Dr. Death.

When someone considers the life of another person is not worth living then that person makes a "moral judgment" which is not in accordance with the principles of bioethics. But in Netherlands the aged society is divided. A section of the elderly population has opted for assisted suicide (Azariah, 2010) while another section of the elderly carry cards with the message "do not euthanize me" (Yee, 2011 a). They are terrorized.

The elderly are terror stricken with fear

9/ **Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies?**

Yes. When discussing about the positive attitude to compulsory euthanasia it is stressed that family support is one of the essential ingredients for aging well.

The positive approach according to Dr. Michael Grodin, a bioethicist at Boston University's School of Public Health, is to provide “the best health care including hospice, pain medication and family support” and not assisted suicide in dying (Boston Channel, 2011). American society can easily provide the first two solutions but not the third solution – family support! The thematic words like family, marriage and home are undergoing radical change.

**10. What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development and (iii) deploying emerging biotechnologies in either the public or private sector?**

Two areas have affected policy decisions. They are food and human health. Although we talk about environment it is clear that no society is willing to downplay its technological comforts. Policies are put forward to eradicate poverty. But the human hunger is ever growing. Human health especially the reproductive health is linked with food technology. Infertility is growing among human population. One affects the other. In most cases market economy comes into play.

**11. What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?**

The most important ethical principle is - “do no harm”. But in the emerging biotechnologies we do not know or do not have the foreknowledge how these technologies are going to do harm. We welcomed the communication technology of cell phones but now it is considered to harm humans with cancer (According to WHO). The recent *E. coli* infection in fresh food items is yet another example. In trying to be healthy we become sick due to contamination in food.

**12. Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realized?**

If we take biotechnology, each country has a Department of Biotechnology and separate body to look into the efficacy of introducing GM food products. Both the governing bodies will not take the responsibility for taking decisions since it is done in the interest of the public and in total ignorance of the future risks.

**13. What roles have ‘risks’ and ‘precaution’ played in policy decisions concerning emerging biotechnologies/**

The recent episode on the conduct of **trials** of *human papilloma virus* (HPV) in India has shown that there were far-reaching ethical violations. The bioethical guidelines prepared by the ICMR regarding the clinical trials involving human participants have not yet been given a legal status. Hence it is “assumed that research team which conducted the project field work should have been aware of all the guidelines and statutory requirements applicable to research on human participants”. Since India ICMR has only guidelines no legal action can be taken on any one and guidelines need not be taken seriously by a research team. The dead will not walk again ( 7 girl participants died) even if there is legal action. An expert committee has been commissioned to investigate the irregularities. The fact finding questionnaire itself is not perfect.

The study was conducted by PATH, a Seattle-based population control NGO with substantial support from the Bill & Melinda Gates Foundation. The expert committee has expressed concerns both at the outsourcing of research unacceptable in the US to other countries as well as the unethical manner in which the trial was conducted. There were irregularities regarding the methodology of obtaining ‘informed consent’ from the 23,000 tribal girls. There were ‘instructions’ from higher ups to the local hostel wardens of these adolescent girls to sign on behalf of the parents or the candidate. In this chain of responsibility who will take the blame? Will the funding agency take the responsibility? Or will any one pay compensation? What is the use of seriously considering the risks and precautions? The funding agency will ask for a report and that can be sent without any difficulty. The project has been closed due to the intervention of the Central Government from New Delhi

### **Latest News on deaths in clinical trails**

Sinha, K., 2011 Clinical trials claimed 25 lives in 2010, only 5 paid compensation. Times of India. Jun 6, 2011, Online

NEW DELHI: Rs 3 lakh – that's the price a pharmaceutical company has paid to the family of a person who died in their clinical trial. Others weren't even this lucky.

According to the Drug Controller General of India's (DCGI) records, 25 people died in clinical trials carried out by nine pharmaceutical companies in 2010. Families of five of these victims received "compensation for trial related death" — the amount ranging from Rs 1.5 lakh to Rs 3 lakh.

**14. To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?**

It may not be possible to regulate with a single framework because the infrastructural needs to be broad based and it is cost intensive. It may be possible to regulate in small clusters with an affiliation to a national or global agency.

**15. What role should public opinion play in the development of policy around emerging biotechnologies?**

Public opinion is a must. But when opinion goes against established values there is a need to stop and think and re-examine the issue.

**16. What public engagement activities are or are not particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?**

When public engagement activities are geared towards a meaningful interaction then it should be encouraged and the policy should have mutual support i.e the governing body and the public

**17. Is there something unique about emerging biotechnologies, relative to other complex area of government policy making that requires special kinds of public engagement outside the normal democratic channels?**

The uniqueness about emerging biotechnologies is that all are focused on human health and reduction of human suffering. But there is no foreknowledge about the emerging risk. Therefore the pace of technological progress should be slow. When untapped technologies are tapped then there is a heavy cost to be paid.