

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'? How have these terms been used by others?

*A: The application of new knowledge or the new application of old knowledge with the intention of benefitting life (plant and animal including humans) on this planet.*

2. Do you think that there are there features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

*A: Most, if not all, emerging biotechnologies are novel and hence, by definition, have not been tried on a large scale in the natural environment outside a laboratory. They have potential for great benefit but also the potential for harm. The potential for harm is unquantified and often unforeseen. The developers of 'emerging biotechnologies' emphasize the positives and often downplay the negatives.*

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

*A In my specialty of Ophthalmology there are several. The classic examples to which most people relate ethically and socially are: Gene Therapy and Stem Cell Therapies, especially embryonic stem cells. However, from my point of view, the under or unrecognized ethical and social issues related to emerging biotechnologies, particularly the successful ones, are their availability, affordability and accessibility. These technologies come at a price and, by and large, the majority of people who need them most often cannot gain access to them because of cost. This is somewhat cushioned in countries like the UK where the NHS covers the cost but, here too, this issue is coming to the fore. Recent advances in lens implants giving distance and near vision after cataract surgery and the use of femtosecond laser in corneal surgery are such examples. These are beginning to expose the gulf between the NHS and the private sector, i.e between the poor and rich social classes with differential access to health care.*

*Ethically, it is increasingly putting pressure on the subject of obtaining "informed consent". Informed consent implies making the patient aware of all the options available to them with their specific risks and benefits, so that the patient can make a knowledgeable choice. Some providers only give information on what is available on the NHS and others on the full range leaving patients disillusioned that because they cannot get "the best" that is out there. Some patients have, on their own account, gone to the extent of raising money to cover the difference (eg between a standard lens implant*

*and the one that gives them distance and near vision) only to be told that they have to pay for the whole operation in the private sector or have the operation on the NHS with a standard lens.*

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

*A: There are many conditions and diseases, for example in Ophthalmology, acanthamoeba keratitis and fungal keratitis (there are several other examples) where the number of patients is very small or where the majority of patients who suffer from these conditions are in poor countries. Industries who invest in such technologies are not interested in developing drugs for these conditions due to expected poor returns.*

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

*A: Not in Ophthalmology, other than the general resistance to genetic manipulation and stem cell research. Even for these there is not a great deal of public resistance.*

6. Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

*A: Regional regulations (eg CE mark) have delayed or restricted marketing of some emerging biotechnologies in Europe. One example of this is the drug Restasis, which is freely available in the USA but not in the UK and Europe.*

*Ethically, my impression is that many companies are looking to undertake early research in humans in the emerging markets or developing countries where the laws are relatively lax and compensation for adverse events is comparatively less. Thus patients in clinical trials in these countries are exposed to the risk whilst the companies mitigate their risk and increase their gain if the product comes to the market in the developed countries.*

7. How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?

*A: War drives technological research a lot of which eventually find applications for civilian use including medical use. Lasers are a classic example. Likewise war generates demands of its own, which drives research to meet this need. An example is the development of the "amniotic membrane" for use in the war theatre. Most of the current protocols for storage of the membrane for ophthalmic use require freezing at -80 degrees centigrade. Research is underway to develop a protocol for storage at room temperature so that the membrane can be readily used at the front line to treat eye injuries.*

8. Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

*A: The long term consequences and potential adverse events that can occur when used on a large scale, is the most important issue. For tissue regeneration with cells modified in the laboratory, whilst the potential is good, the risk of some of these cells assuming 'cancer like' properties in the host is one example.*

9. Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

*A: Yes. As mentioned above, the social divide and tensions created by availability of the benefits to the rich and not to all is to me a major issue that needs to be considered.*

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?

*A: Cannot comment.*

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?

*A: All emerging biotechnologies, should be deployed under strict conditions where in data is continuously gathered and patients monitored for several years after introduction. This is largely done in many cases (NICE guidelines) but should be applied everywhere in the world, wherever the 'developer' chooses to carry out the initial trials. At present, in some countries, the laws are weak and exploited.*

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 realised?

*A: The responsibility should be collectively assigned to Scientists, clinicians, industry developing the technology and government regulatory departments. The lay public should be involved only once the evidence is robust. Lay individuals often tend to ignore evidence and be more emotional, driven by personal social, cultural or religious beliefs.*

13. What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

*Cannot comment*

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?

*A: There are common aspects generic to most emerging biotechnologies and then there are specific considerations for individual technologies, hence a combined approach of a triage by a single 'framework' or body followed by a more specific 'framework' or body with specialist expertise in the related field or cluster of fields.*

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

*A: Covered in 12 above.*

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

*A: Knowledge and correct information is the key to successful public engagement. Religious and cultural leaders should first be educated as a separate exercise before engaging the public.*

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

*A: Yes, as emerging biotechnologies directly affect or can affect the individual or his/her children, the level of public interest is generally greater. People jump to conclusions or are easily swayed one way or the other as they have limited or no expert knowledge.*