

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.

# Nuffield Council on Bioethics Consultation on Emerging Biotechnologies Response

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## **1 How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?**

Interestingly, despite working in this field I have never given it much thought and used the terms quite loosely to refer to anything that might be regarded as new for the community in which I live. That said, most technologies have long intellectual and practical histories, so I would hesitate to define what the criteria for 'new' might be. I am aware that in the disciplines of history of technology and innovation studies that there is some debate as to what the criteria for emerging technology might be. As a sociologist, my work on emerging technologies tends to focus on radical transformations in knowledge practices that are capturing public attention and attracting significant comment and engagement from communities. Again, what is emerging for one community might be different for another, but my work is focused primarily on emerging technologies in advanced liberal democracies and the global competition by governments in Asia, Europe and North America to build competitive advantage from investing in cutting-edge biomedical developments.

## **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.)**

Thinking about it now, I guess the key to what I have said above is that emerging biotechnologies have to generate excitement, potential and possibility within the community on a broad scale. At the height of the stem cell debate in Europe, Australia and North America for example, stories about stem cells had a high frequency in news bulletins. So, topicality would be one criterion. Another would be the potential for breakthrough in an area deemed socially and critically important. Improved health outcomes are always a good one, but increasingly, emerging technologies that deal with climate change, energy saving or environmental conservation are others.

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

I work on biomedical technologies and am currently thinking about the implications of stem cell technologies entering the market. From my point of view, the questions of social justice and equity of access are the most important issues. How are new biomedical technologies entering into healthcare systems and how do they map onto already existing inequalities in healthcare? More interestingly, how might new innovations in health care biotechnologies in particular actually address health inequalities in the first place? The female condom is one example I can think of – designed as a means of allowing women to have more control over protecting themselves in sexual encounters, the female condom at the time of its introduction to the healthcare market was seen to be a revolutionary breakthrough in addressing a persistent problem in healthcare – that sexual encounters often involve a complex power dynamics that leaves some

people more vulnerable than others. But was this an emerging technology or simply an insightful innovation?

The much vaunted holy-grail of human stem cell research – to find cures for Alzheimer's, Diabetes and so on, would have a significant impact on population health for those who lack access to medical care. But are these really achievable goals in the first instance? Who would pay for the treatment? Will there be ongoing requirements for continued treatment, in which case maybe more established treatment methods are just as effective for disadvantaged populations. For now, some of these questions cannot be answered.

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

YES!!! There always are. Work on national and regional innovation systems show that there is a significant level of difference in the way technologies emerge in different contexts. Historical, geographical, environmental, political, social and cultural factors all affect how technologies emerge. For example, much work on ICTs has shown how countries that have geographically dispersed populations and/or lack already existing infrastructure have adopted mobile telecommunications much faster than in countries where the opposite is the case.

Or; different cultural meanings attached to embryos have for a long time meant disparate regulations around the world, often argued to be responsible for a brain-drain of highly skilled researchers and a lack of junior researchers.

Interestingly though, there is little empirical research supporting such claims, although there are some well-noted examples of individuals relocating elsewhere

as a reaction to government regulations where they were. Overall though, the most that these regulations do, I would argue, is provide governments at the national and regional level with opportunities to exploit such differences for their own political advantage so that they can be "seen" to be caring for the future health of their populations whilst at the same time promoting their region/nation as a hub of cutting-edge activity in the hope of attracting further economic investment.

In the case of stem cell research in particular, the same disparate regulatory arrangements from country to country have also been argued to be driving "desperate" patients overseas for treatment unavailable at home. This claim is somewhat contentious and lacks solid evidence as to what the motivations of patient's actually are and whether or not they are being pushed to go overseas. Preliminary research conducted by Petersen, Sears and Munsie in 2010 demonstrates that often patients are in fact well aware of the risks associated with what they are doing, but are willingly undertaking these risks anyway.

To me this suggests that at some point with any emerging technology, there has to be an avant garde, or group of individuals prepared to make their own decisions about what they are willing to do. In terms of mobile phones this is a relatively neutral point and such folk are referred to in the technology literature as 'early adopters'. But when it comes to medical technology there is an extra layer of government intervention that makes being an 'early adopter' somewhat more problematic. I don't think judging people who undertake untested treatments as victims of exploitation is particularly productive. Again, further research is necessary.

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

GM Food in Europe is the classic answer to this question. Community resistance to the use of genetic modification in foods resulted in a resounding trouncing of the attempt to introduce GM crops into the European food system. The European GM food debate has had flow on effects in other countries as well, with many community organisations in advanced liberal democracies actively lobbying for changes to food labelling laws such that any GM products must be clearly identified.

I can't really think of any other examples that have resulted in outright rejection of an emerging biotechnology by a 'public'. It seems more that there are certain groups of people who might raise objections, but that when it comes to developing community regulations ultimately the argument that the society is a pluralist one and that it therefore seems unfair to outweigh the potential good for all members of society just because of some concerns by others. While on the face of it, this seems like a utilitarian argument based on the 'greatest good for the greatest number', in practice it seems more that more radical opposition to emerging technologies is typically regarded as overtly zealous therefore of little consequence for most people.

In relation to medical biotechnologies this argument goes: scientists are trying to find cures for terrible diseases, some community groups resent the way that scientists are doing this, politicians decide that these community groups don't represent the whole of the community, therefore in the absence of any more compelling data on which to base these decisions, they generally assume that medical progress is good. There is very little critique of what should be defined

as 'progress'. It seems rather that the scientist's promise to find cures is enough. Some research conducted in Australia (Diane Nicol, Don Chalmers, Christine Critchely) has demonstrated that there is a particularly high level of public trust in science in Australia that is not echoed elsewhere, and that these high levels of public trust might be a determining factor in the lack of critique of scientific research.

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

Yes of course. In stem cell science in particular, research mapping shifts in regulation over time shows that countries that may have started off with restrictive regulations have moved to more progressive regulations over a relatively short period of time. I haven't seen such a map recently, but I think that you would find that the regulations are generally homogenising globally over time.

When looking at developments in innovation too, some key researchers argue that innovation is done globally. They argue that access to the best international research, strong networking opportunities and the global flow of people and resources within these networked scientific communities means that innovation is done on a global scale. This is supported by evidence in regional innovation studies that argues that the movement of personnel from one location to another, especially postdocs, are significantly important factors for the development of particular technologies.

Intuitively, this also makes sense. That is, everyone networks with people that they know through family, friends, neighbours, former work colleagues and so on in order to find gainful employment and new challenges in their professional lives. Sometimes networks are simply a function of someone's spouse's work, extended family obligations or a preference for being in a better climate, closer to the beach or having less commuting time. New employees thus bring their prior expertise and established networks to a certain location. This has also historically been demonstrably true in countries at the global 'periphery' for a very long time. Indeed, governments have long attempted to exploit these parameters in order to build a workforce in a certain location. In the stem cell sciences in particular, the governments in India and China have built specific policy platforms around convincing star personnel to return home after a period overseas.

As someone who has worked both in 'the periphery' and 'the centre' I would also add that while individuals, communities and governments in countries in the periphery have long been aware of the benefits of migration between the periphery and the centre and actively looked for ways of maximising the benefits so obtained, the reverse rarely holds true for the centre. The centre, by contrast, tends to view migration patterns as a question of border protection, effectively setting up exclusion zones for people on the other side of the border. Where migration is encouraged, it is only with the view to filling jobs that no-one else wants to do. This is incredibly short-sighted to say the least, and countries in both the periphery and the centre would clearly benefit from more active engagement and support of the networking opportunities provided by the global movement of peoples and populations.

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

This is a little outside the sphere of my research, but from what I said above, liberal democracy tends to be the overriding principle adopted in negotiating emerging technologies. Some theorists in Australia and Canada though have contested the processes by which governments make decisions, arguing that a more 'deliberative' approach to democratic decision-making would allow for more community participation, thus making otherwise elitist processes more democratic.

In Australia in particular, so-called community consultations are usually conducted via a system of inviting selected stakeholders to one or two day events. A call for a community consultation is initiated in parliament, sometimes via a parliament members own initiative, sometimes in request to lobbying by members of their constituency. The request is considered and debated by members on whether a consultation is necessary. A special committee is formed and the Committee secretariat – usually consisting of individuals selected from a pool of government employees – does the detailed work. Usually in the first instance a consultation paper is developed and promoted in the media and through channels that will target designated stakeholders. Responses are invited to be posted to the Committee and then from these, relevant respondees may be invited to participate in further workshops.

While this is a process that in theory, allows everyone who wants to, to have a say, in practice it means that views from the most powerful stakeholders are



given more weight than an individual response from a member of the community. How this might be negotiated is something taken up in work on 'deliberative democracy'. In Canada, the suggestion that round table discussions be held with all the different sub-sectors of the community be conducted so that a more representative range of views might be included in community consultation (Edna Eisendal and co). In Australia, research on deliberative democracy has mainly explored the question of representative the stakeholder process can really be regarded (Sue Dodds and Rachel Ankeny have been working on this question).

**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?**

I think that the ethical and policy issues are specific to each technology. While there are some issues that may turn out to be applicable to a number of technologies, I think generalising for each technology is the wrong approach. I would advocate a kind of framework approach to systemically identifying and addressing each issue and exploring whether or not it fits for a given technology. While this may sound time-consuming, I think that dealing with each emerging technology in its specificity is the only way that ethical and policy issues will be identified.

For example, the development of recombinant DNA in the US in the 1970s was something that was seen as somewhat of a game-changer in terms of the technologies that came before it. In the history of technology this was a

significant moment, because scientists working in the field themselves got together to discuss what exactly it was about rDNA that was so challenging. Similarly, the use of IVF in Australia in the 1980s prompted the world's first community consultation and regulatory recommendations for what some of the ethical and political implications would be of the widespread use of IVF technology. One criticism though is that the consultation only occurred *after* the technology had been made available, so the committee was forced to limit its inquiry into actually existing uses and did not have the breadth and scope of an inquiry that might we might expect of an emerging technology. GM Food, cloning, stem cell research etc are some of the more recently emerging biotechnologies that have been debated and discussed, but one would be foolish to suggest that they have any parallels that would allow these issues to be considered 'the same'.

For instance, although patenting might be regarded as something affecting all biotechnologies, I would argue that the issues are different and dependent on what is in fact being patented. Again, I reiterate my earlier point that the policy issues that I think are most important with any emerging technology are impact on the community in terms of decreasing existing inequalities. That is the biggest policy issue for me and as far as I am concerned one that is ALWAYS overlooked in terms of emerging technologies until a well-entrenched increase in inequalities becomes a political issue that is unavoidable. Equity of access to IVF technology in Australia was only challenged in the courts by individual patients who were prepared to pursue the issue. This is not good enough – the policy implications should be recognised and redressed from the outset. "Shutting the gate after the horse has bolted" is always poor policy.

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

Again, as I've mentioned above, for me the biggest issue is how emerging biotechnologies are going to help the most disadvantaged members of the community. There is very little discussion or debate about why emerging biotechnologies are so important – it seems simply that they are 'good' because they represent progress. For me, progress would equate to reducing social inequalities, not increasing them as so often happens with the introduction of new technologies. I think more investigation of the numbers of people expected to benefit from an emerging technology and what particular issues are going to result for the most disadvantaged is the most pressing issue that should be discussed in focusing on a new technology. Unfortunately I think that rather than policy issues being addressed at all, ethical issues tend to take precedence in discussion of new technologies, and I think this is in fact the wrong way around. Ethical issues are important but always seem to get stuck in an impasse of whether or not something is right or wrong. The question should be reframed to ask: in what ways does this technology benefit our community and how?

## **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?**

In the stem cell sciences, some people argue that regulations in the US banning the use of federal funds for research involving the destruction of human embryos has pushed researchers to find more ethical means of conducting research

without using human embryos. Others have argued that the same ban has been detrimental to the progress of stem cell science and resulted in the US falling behind in the stem cell 'race'. Most notably, the ban on Federal funding has prompted changes in state laws surrounding embryonic stem cell science, resulting in quite large sums of money being allocated for stem cell research in several states in the US. The most famous of course is California's Proposition 71. One of the side effects of the federal ban on funding resulting in more state funding for stem cell research is that it could potentially be argued that there is a lack of competitiveness in funding. There has been some research that suggests that there are so few researchers doing embryonic stem cell research in California that the funding body is actually struggling to find good projects to fund and that a lot of the money is being wasted. I think that at the time the California funding was established they assumed that researchers would flock to California to utilise this opportunity and they would be inundated with innovative proposals to choose from. This has not transpired so far, suggesting that there are more issues to think about for emerging technologies than a permissive regulatory environment and more funding. Without doing more research on this particular issue myself, I don't know why the funding has been so difficult to distribute. Adequate infrastructure and research facilities has been one issue affecting the distribution of funding mentioned in the literature. I would suggest too that researchers are hardly likely to relocate for short-term funding unless they are at the postdoctoral level, so perhaps the idea that high-profile researchers would be attracted to California because of the money overlooks the complexities of why researchers might relocate.

## *Ethics*

### **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?**

I think the 'precautionary principle' has to be the key issue underpinning the development of any emerging technology. That is, what are the risks and benefits going to be of this technology becoming more readily available? Who or what is going to be most affected by its availability? How is it going to address social inequalities and what impact will it have on the environment? I think the key ethical principles guiding new technologies should be based on benefits outweighing the risks, but not on an individual level, on a social and an environmental level. Under contemporary neoliberalism it's far too easy for developers, distributors, regulators etc to say, we're just putting this out here, and if people want to use it it's their choice. I think that to live in a just and fair society then the principle of individual choice has to be balanced against the greatest good for the greatest number *and* environmental sustainability.

### **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?**

Clearly this is somewhat problematic, as depending on what point the risk is realised is going to depend on who has an incentive to publish risk-disseminating information. I would like to see a greater role for public ethics advisory bodies in researching, analysing and disseminating risk information. It would also be helpful

if such public bodies had more influence over government decision-making such that if risks were identified then they would feed more directly into regulation. There would have to be clear guidelines about how this might work, such as transparent evaluation processes, opportunities for contesting the assessment, a rigorous conflict of interest policy and a more community focused concern on the development of emerging technologies. I think overwhelmingly at this stage that raising awareness of risks about any emerging technologies relies too much on individual whistleblowers and/or community advocates. While this has been very effective in different contexts, overall it is usually a slow process building enough support for community action campaigns.

## *Policy*

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

I think in the EU the precautionary principle is adopted much more than in other countries. In Australia and the US for example, regarding human embryonic stem cell research in particular, the precautionary principle was not used, nor was any measurement of risk adopted. Overall, in these locations the main evidence presented for policy decisions has come from community representatives regarding moral values. Notably, these community groups do often disguise their claims as precautionary based, but in practice they are morally driven based on what the group they are representing thinks is right. For instance, hESC research has been argued to be a slippery slope to the treatment of humans means to an ends. Yet there is no evidence for this other than the moral justification that embryos are human, therefore using embryos as a means to an ends is the same as using humans as a means to an end.

#### **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?**

I am not sure that a singular framework could ever work for emerging biotechnologies. Perhaps you could have one department responsible for regulating the technologies, because there would be a lot of cross-over between them, but you would have to have specialisations in each technology. Maybe you could have a Department of Biotechnology that had five main divisions: agriculture, food safety, human health, environment, and security. This way you would have a lot of cross-over expertise between biotechnologists who have the scientific experience and you could also have regulatory power to apply a broad-based risk assessment framework to any emerging biotechnology consistently across all five divisions.

#### ***Public engagement***

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

Clearly public opinion has already played a significant role in the development of policy around emerging biotechnologies. I think that there is actually far more scope for public opinion to be included in policy decisions. There is not enough evidence-based decision making at the policy level about what the community wants.

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

Random telephone surveys of the community are not helpful because the community often doesn't know that much about the technology they're being

asked about. Focus groups, where the facilitator can include explanations of what the emerging technology does, are far more useful but are also more expensive. I think the stem cell experience has shown us too that public engagement events along general topic lines always end up reproducing what's been in the media in that location. Public engagements would be more useful if they could focus more explicitly on particular issues in relation to the emerging technology. You could have something more specific like: "Indigenous Australia and emerging healthcare biotechnologies" that focused on a range of emerging biotechnologies and their impacts on particular groups in society. This would be far more engaging than "Stem cells: everything the community needs to know". The first example is specifically addressing issues that impact on a community, whereas in the second example, you end up with an undefined notion of community that ends up being by default white and middle-class. To sum up, the key point is that for community engagement to be effective, it needs to really focus on specific issues rather than generalisations.

On this point, I would like to say that community engagement along the lines of "Stem Cells and Ethics" is completely useless. Community engagement like this is typically based on "the public deficit" model of public understanding of science, where it is assumed that the community doesn't know anything about the topic being discussed therefore it's up to these forms of public engagement to act as education programmes. This doesn't work with adult populations who already have a sound moral framework for making their own decisions about things. All you succeed in doing is reiterating the point long established that some people view human embryonic stem cell research is unethical because it uses embryos and that other people think that any progress in medical research should override these claims about the moral sanctity of the human embryos. In other words, instead of engaging the community, you simply provide an alternative



forum for people with strong moral views about the topic to air their opinions. If you had a more specialised and narrowly focused topic on specific issues to do with emerging biotechnologies than you find more meaningful engagement with the community.

**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?**

To be honest, I really don't think so. I think any emerging technology should be assessed in the same kind of way as emerging biotechnologies. I also think what I have said above about community engagement, risk assessment, the precautionary principle and deliberative democracy applies to all forms of democratic negotiation, regardless of what the issue is.