

BOX: continued

Meanwhile, western researchers and governments frown upon those same therapies as dangerous, maverick science that conforms neither to standard safety procedures nor quality control measures. But India is also moving into bona fide clinical trials of stem cell therapies at a rapid rate. And its research institutes are places that western scientists are increasingly keen to do business with.

India's research institutes want to do business with western scientists, too. According to Peter Glasner, whose work at Cesagen has tracked the fates of "spare" human embryos from their point of conception in Indian IVF clinics to their use in stem cell research around the world, these international collaborations bring mutual benefits. Indian labs get access to important skills, knowledge and training for their scientists and technicians. And scientists in the West, where research is constrained by the limited availability of human embryos, are looking to tap into the plentiful supply of such material on the Subcontinent.

But to sell embryos to private US research labs, or to deposit stem cell lines in the UK's Stem Cell Bank, India has had to conform to the host of western regulations and protocols that govern the standards of production, quality and ethical provenance of human eggs, embryos and other tissues used in research.

To make its stem cell lines and embryos fit for western consumption, the Indian government has drafted guidelines for its research community, in the form of regurgitated versions of the UK's Human Fertilisation and Embryology Act, Stem Cell Bank protocols, or US regulations. The result, says Glasner, is a moral economy in which the ethical values of the West have been exported to India and elsewhere in order to support and encourage the donation of abundant, and "ethically clean" material. Hence, just like in the US and UK, the only embryos that can be used for stem cell research in India are those that are surplus to the requirements of IVF. As Glasner's colleague Aditya Bharadwaj puts it: "That is a surprising requirement in a country that does not have the religious baggage that protects embryos being created specifically for stem cell research in the US and UK."

Other problems arise when those ethical values, and the guidelines and regulations that enforce them, are reinterpreted through Indian culture. For example, western regulations demand that eggs and embryos are obtained with the full informed consent of donors undergoing IVF treatment. That might be relatively straightforward in the UK, but it doesn't necessarily export well, and in other cultures, obtaining informed consent can amount to little more than a ritualised formality.

"In a situation where the woman does not have a voice, is not allowed to speak in public, is accompanied to the consultation by her husband and parents-in-law, has no education, and for whom the form has to be translated before she signs it, the cards are stacked against that being an appropriate way of getting informed consent," says Glasner. "And this is not an uncommon situation in India." And in a nation where infertility carries a profound social stigma, Indian women desperate to get pregnant are open to exploitation by a fertility industry keen to procure more eggs and embryos for the purposes of research and trade.

The export of the regulations and guidelines, which are intended in part to ensure the ethical provenance of the stems cell lines and embryos, serve to conceal these cultural complexities. As long as those standard procedures are seen to be adhered to – as long as the boxes have been ticked that informed consent has been obtained, for example – the west can use whatever stem cell materials are provided without having to think about their history. Indeed, by the time those materials have been incorporated into the western research machinery, they no longer have a history, says Glasner, only a future.

And yet if the benefits to global science of the trade in embryos and stem cells is not to come at the expense of people at a more local level, regulators at both ends of the supply chain need to appreciate the true complexity of that history.



Globalisation and Governance

Globalisation is both objective and subjective. It's objective because – more and more – economies and markets, cultural products and communications are literally global. People collaborate across the globe in generating goods and services while producers try to target a worldwide audience. But it is also subjective because a key aspect of globalisation is people's recognition of their global interconnections. In part globalisation comes about through people thinking of the planet or of global bodies (UN agencies for example) as entities to which they have responsibility or of which they have hopes.

Though genomics appears to be about individuals and their differences, there are surprising ways in which the new life sciences contribute to both the subjective and the objective aspects of globalisation.

One key aspect of the subjective element concerns the way in which genomics contributes to cultural appreciations of the connections between people and our global similarities. Genomics research not only produces information about the enormous degree of similarity between all the people alive today, but allows individuals to trace the way that their ancestors likely traversed the globe. Genomics research helps us to envisage humanity's global interconnections in novel and unexpected ways.

The objective component of globalisation is revealed by analyses of the ways in which new forms of trade in human genetic information and novel therapeutic treatments make surprising links across the world. We have all become familiar with "treatment" tourism, where people travel – often across continents – to get medical treatments unavailable or unaffordable in their own countries. Entrepreneurs are now advertising holiday-and-treatment packages to resort destinations where advanced medical procedures are also on offer and where one can convalesce in 5-star luxury. Medical practitioners and researchers can also travel to find the most conducive or profitable locations to carry on their work.

Globalisation does not mean global uniformity

People's ability to travel in order to receive treatments or to practise medicine or research also has an important impact on the way that regulations and standards can be made. Sovereign nations can determine their own policies for genomic research and medicine. But if these policies are in danger of being widely avoided by people going overseas, they will be undermined and made to look untenable. This indicates one of the ways in which globalisation is expected to progress: globally-mobile customers and businesses will move to areas where regulations seem most favourable, and other countries will be under pressure to follow suit in re-drawing their own regulations.

Writers on globalisation have pointed out that global pressures do not necessarily lead to global homogeneity. Such processes may instead foster differentiation since different locations can cater for different preferences or ideologies. Similarly, the mobility of investment funds and skilled labour may mean that existing inequalities become magnified. Already wealthy areas may become yet more favoured while poorer areas see their more talented citizens leave.

Reflecting the significance of these global trends, the ESRC Genomic Network's research effort is itself an appropriately global undertaking, with research projects based in Venezuela, South Korea, India, Eastern Europe, Brazil, China, Vietnam, Kenya, South Africa, among many others, as well as in the UK. And many of those are concerned to a greater or lesser extent with the process of globalisation, and how it interacts with governance in the realm of genomics and biotechnology.

Two key examples refer to the global trade in stem cells and to international manoeuvres in the patenting of genetic material. Both deal with ironies and unexpected twists in the way that national governments, citizen organisations and entrepreneurial actors respond to the opportunities created through globalisation.

The ESRC Genomics Network (EGN) is dedicated to examining the social and economic consequences surrounding the development and use of the science and technologies of genomics.

The EGN includes 3 ESRC funded Genomics Centres - Cesagen, Egenis and Innogen – and the Genomics Policy and Research Forum. These investments range across 5 universities, and involve over a hundred researchers, from professors to PhD students, as well as administrative and support staff and a rotating cast of visiting research fellows. The Network is one of the largest social science investments in the ESRC's current portfolio, and is growing into the largest concentration of social scientific research on genomics in the world.

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Globalisation of ethics and morality

We expect “human rights” and similar ideals to be universal. But the case of stem cells shows just how complex it can be to try to harmonise ethical ideas. India, China and some East Asian countries have surprised the west by their rapid advances in human stem cell research, often assisted by apparently different cultural attitudes to the embryo and to the doctor-patient relationship. Western researchers have been stunned by these advances, particularly since work on human stem cells has seemed so ethically complex in Germany, Italy and large parts of the USA.

Network researchers have followed up on these advances, looking both at how stem cell work is conducted in India and elsewhere, and at how global processes have impacted on research and therapy.

Indian researchers and therapists seem torn between sustaining the practices they have evolved themselves and entering into global – supposedly more “universalistic” – relationships in which their practices are required to conform to the international community’s notions of informed consent. Western notions of informed consent may threaten their customary ways of working and disrupt dealings with patients and their communities, thus impeding medical progress. Yet the ability to attract western partners and investment is seen as an attractive way to develop the researchers’ and therapists’ work. Network researchers have explored just how this works out in practice (see Box).

Equal complexity is evident in matters of patent protection. Patents are a western idea and practice that is spreading globally. Without patent protection, many firms and entrepreneurs may be too cautious to spread the benefits of their work across the world. But patents may not fit all situations equally well and may introduce new kinds of inequality and unfairness.

Cesagen research has examined the way that communities in areas with abundant genetic resources (in local plants for example) have responded to the emerging global ideas about intellectual property and its ownership.

Of course, many of these communities do not themselves operate with anything like an idea of intellectual property. They may insist that such things cannot be owned. But then how do they respond to firms and their lawyers who try to engage them in novel property relationships?

Paul Oldham of Cesagen has worked for several years in South America. He suggests that most indigenous peoples wouldn’t know that the patent system exists. Those that do know generally take a dim view of the idea that plants and other life can be transformed into private property, and would question the inter-

ests that it serves; this is why we have mobilisation around the concept of biopiracy – from indigenous peoples organisations and NGOs.

The International Indigenous Forum on Biodiversity mobilises very strongly around these issues. Recently Oldham attended the UN General Assembly for the adoption of the UN declaration on the rights of indigenous peoples, which has been 22 years in the making. Article 31 states that indigenous peoples do enjoy rights to genetic resources and associated knowledge. The question now is how this claim will be taken forward. People are already arguing that there should be an ethical code of conduct under the convention to guide research practice amongst indigenous peoples, including IP issues. They are pressing also for the disclosure of the origin of the material and knowledge from indigenous peoples. The target is to have a decision on that in the form of a new agreement by 2010.

Paul Oldham observes that one key problem is that intellectual property and claims about intellectual property are very difficult to “see”. In response, people and governments will understandably begin to mobilise to protect themselves in various ways. This can take the form of legislation (as in Brazil where biopiracy is accompanied by criminal sanctions), or more generally, a growing climate of suspicion that focuses in particular on researchers. Thus it has become increasingly difficult to carry out research with indigenous peoples in places such as Amazonia even where there is no intention to commercialise the results of the research. In this sense concerns about intellectual property begin to impact everyone.

Across the world different strategies have been worked out in response to the same ‘global’ threat. India has established a traditional knowledge database as has China. The idea is that this heads off patenting in the west because it is prior knowledge and thus unpatentable. In Venezuela there was an attempt to establish a database but it was difficult to secure its widespread acceptance and there were fears that something originally intended to protect people’s interests could rapidly take off in a commercial direction. People became uneasy with the very instrument that was devised to supposedly protect their interests.

Do patents fit the life-science case?

As well as problems with the international application of patents, Network researchers have identified difficulties with the overall suitability of traditional patents for the new life sciences.

Jane Calvert of Egenis and Innogen points out that the patent system tends to view genes as a discrete stretch of DNA that can be shown to have clear causal effects on an organism’s biology. The genes are the origin, so to speak, and that’s why

they can be patented. But Calvert argues that this linear model of gene function lags behind the more sophisticated picture that has been emerging from modern life sciences. Genes are increasingly recognised as having multiple functions, while the traits exhibited by organisms are viewed more as the product of a network of interactions between multiple genes, cellular physiology and environmental influences.

Patents give rights over all the functions of a gene that is patented – even those not yet discovered. There have been cases where patents have been granted on a gene implicated in a quite trivial function, but which turns out also to play an important role in the physiology of, for example, HIV. In such cases the patent can make use of the material enormously expensive and thus block the development of research.

Moreover, while the patent system treats DNA as any other chemical compound that has been isolated and purified, biologists increasingly deal with it as information rather than matter. Indeed, the sub-discipline of bioinformatics, which applies computational techniques to biological problems, is of central

importance to genomic research, and DNA has uses over and above its biological effects on an organism – establishing evolutionary relationships between taxa, for example. The relationship between biology and the computer sciences is growing so close, says Calvert, that “I think I’m going to be studying IT rather than genomics in the future.”

Calvert notes that some have argued that the nature of genomics systems better fits a different ownership paradigm from the conventional patent – open source comes to mind as a clear alternative. Given the worldwide success of some open source ventures on the Internet, there is an intriguing fit between the globalisation of the new life sciences and open source models of ownership.

BOX: Stem cells for sale

Regulations can work in mysterious and unpredictable ways when it comes to global scientific endeavour, as demonstrated by Network research on international stem cell science. Take the differences in regulation between the UK and Germany, for example. In the former, research efforts concentrate on embryonic stem cells, which have a greater potential for differentiation into other cell types – and, in theory, a greater potential for therapies - than those derived from adults, and UK regulations permit research using very early embryos that are not selected for implantation during IVF treatments. In Germany, however, the country’s history led to an increased sensitivity regarding research on human subjects, and pre-implantation selection of embryos is deemed sufficiently redolent of eugenics for the practice to be prohibited. (In German IVF treatments, only three egg cells may be fertilised at a time, and all must be implanted.) So, scientists there have had to make do with adult material for research. But while UK research efforts have yielded little in the way of therapies, the German pipeline is starting to deliver. One potential treatment for hearts damaged by myocardial infarction is now attracting great interest from heart surgeons in Britain.

“Regulations not only constrain science, they also force it to be creative,” says Egenis’s Christine Hauskeller, who is comparing the development of stem cell science in European countries that differ in social and regulatory frameworks. “In the field of stem cell research, you really can see that science is a global enterprise, because it is conducted in different ways in different places.” The result is a global mosaic of scientific research, where the whole is more productive than would be likely if regulations were internationally homogeneous. “You could say that everything that people want to study, can be studied somewhere,” she says.

Elsewhere in the world, regulatory frameworks governing stem cell research are virtually non-existent. India, for example, has a more relaxed attitude to some issues that are seen as ethically problematic in the West. There, the prevailing view that ensoulment of an embryo occurs at implantation makes it hard to view an embryo in a Petri dish as anything more than a clump of cells. Other moral and ethical considerations, such as those to do with the safety of new treatments, tend to be swept aside amid a widespread desire for biotechnology to replicate the successes of the Indian IT industry.

While countries in the developed world debate the ethical issues involved in stem cell research and treatments, India is just getting on with it. And in doing so, it is getting itself a reputation - in more ways than one. A steady stream of wealthy western “medical tourists” with incurable degenerative conditions are being drawn to the country by experimental, suck-it-and-see therapies being offered by many private clinics, in the hope that they might walk again, see better, or breathe properly. (And many of them claim that the treatments have indeed helped.) **continued**