

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.

### **Emerging Biotechnologies and Regenerative Medicine**

The term “emerging biotechnologies” is being used more and more in the literature and in the news, but in some cases people using these terms are not aware of what they represent or where they could lead us. The unawareness of common people, as of what the advantages and disadvantages of the emerging biotechnologies could be, makes them either skeptical or overenthusiastic towards these matters. For example, when the term “regenerative medicine”, which we are going to analyze further in our discussion, is used in the media, people think of a new type of medicine that can heal everything and keep us young forever and they are looking forward for using this technology. Of course the potentiality of this emerging biotechnology is enormous, but our knowledge is still limited as to whether and when we will be ready to create a whole brand new organ in the laboratory.

The identification of adult stem cells paved the way for a whole new world of “emerging biotechnology”, the regenerative medicine. Devoid from the ethical issues related to the use of embryonic stem cells regenerative medicine, which could use adult stem cells, promises to change the practice of medicine. Adult stem cells are physiologically found in the adult tissues as an essential component of tissue homeostasis, maintaining normal turnover of regenerative tissues. They also serve as a repair system for the body replenishing specialized cells lost due to natural cell death (apoptosis) or injury. The idea of the regenerative medicine was conceived when scientists managed to isolate the adult stem cells from adult organs and upon stimulation with appropriate factors to make them differentiate into specialized cell types, in culture.

The understanding of the biology of stem cells will allow the repair and/or the replacement of damaged or old tissues and organs. First of all we should make the distinction between the two branches of the regenerative medicine. Regenerative medicine could be conceived as the use of stem cells to stimulate the organ to start its homeostatic repair mechanism and heal itself and/or the use of stem cells to create tissues/organs in the laboratory and safely implant them in the patient replacing the old tissue/organ with brand news.

Of course the benefits of regenerative medicine are enormous and currently the clinical use of mesenchymal stem cells is exploited in a number of degenerative and inflammatory conditions, while the use of hematopoietic stem cells is a common clinical practice for the treatment of malignant and nonmalignant hematological and other diseases, that has improved the life of many patients and has healed many congenital disorders. Here we should point out that the use of stem cells in such situations has not been free of ethical misconducts. For example in the developing countries many companies are promising to

heal congenital disorders, such as Down syndrome, with the use of stem cells that it is a real science fiction. The use of stem cells may alleviate some symptoms, but it cannot heal the cause of the disease.

Another issue that emerges is how the cultural and political system influences the advancement of the emerging biotechnologies. In the example of regenerative medicine the ban of stem cells use in research has hindered the acquisition of knowledge necessary for the development of the regenerative medicine. For example another potential source of cells are the iPS cells (induced-pluripotent stem cells), that were first discovered in Japan; a country where the law regarding the use and study of stem cells has been always been less restrictive. It is possible that if the use of stem cells for research purposes was allowed in US and other European countries earlier, a more competitive environment would have been created; accelerating the acquisition of knowledge on stem cell biology. Under these circumstance our knowledge would have possibly been could be more advanced by now.

On the other branch of regenerative medicine, our knowledge, however, as to how to create a whole new organ ex vivo, that would potentially solve the problem of the organ shortage available for patients that require organ transplantation, is still limited. Not only is our knowledge regarding the biology of stem cells and their interaction with other cell types limited, but the lack of the appropriate scaffold in which these cells could grow is also a limiting factor. This knowledge could be only provided by other scientific disciplines such as bioengineering and nanotechnology, pointing out the fact that emerging biotechnologies depend on each other and the development of one requires the growth of the other.

But even though we conquer the knowledge and we are able to recreate a whole brand new organ in culture there are multiple ethical issues that emerge. First of all who has access in this new advancement? Our knowledge on the biology of stem cells is still limited to declare that we can produce a whole organ from scratch just by using stem cells that would be appropriately differentiated. And even if we reach at this level the cost of production would be enormous. Thus, only rich or privileged group of people will have the access to this beneficial product?

Furthermore, which is the best source of the stem cells and when should we isolate them? Recent studies have shown that stem cells (at least the hematopoietic stem cells in mice) do age. This postulates that the earlier we isolate these cells, the better quality they would have when we need them. Does this means that children whose parents have preserved their own cord stem cells would be the first to benefit from new therapies? Does this mean that we all should keep our stem cells when we are born for future use? And what the personal cost would be and the cost for the whole society would be? And here we have to mention the issue of the stem cell banking and how the emerging biotechnology of the regenerative medicine will influence the need of storage of the stem cells. Of course here there are multiple ethical issues that have been analyzed multiple times regarding the stem cell banking: if the banks should be private or public, what are the regulations that such a bank should follow, who is responsible for supervising these banks etc.

Another issue that arises is when are we going to be able to use these brand new organs? Is it enough that a group of scientist verifies that they are able to recreate a new organ in the

laboratory to allow the wide selling of these organs or does society need other reassurances before using these “regenerated” organs? For example, how safe are they and what are the risks of rejection (even though regenerative medicine promises to solve the problem of immunological transplant rejection, since the organ's cells will match that of the patient, there could be other complications in the procedure or the rejection of synthetic parts of the transplant), how long is it going to last and what are the options thereafter? What would the setting of the clinical trials, necessary to test their efficacy and safety, be?

On the other hand, laws and legislations should reassure the lack of discrimination that could arise from the use of “regenerated” organs. Are such organs going to be considered “superior” or “inferior” to the natural ones and who is going to define it? Should the privacy of relevant personal data be preserved or should it be revealed to the insurance companies? How will the use of these organs influence the life insurance status of the people that will use these organs?

Moreover, regenerative medicine, with the continuous replacement of damaged and/or old organs, promises that everyone could stay young forever. But is it a society of old “repaired” people that we are hoping for? Can we expect this society to be sustainable, that is, to afford more generations, with the current level of available resources, or in such conditions reproductive decisions of families would become more difficult?

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