

Social and Ethical Issues in Regenerative medicine: towards a governance of ‘bench to beside’

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Discussion:

Regenerative medicine (RM) is still in its infancy and need to be defined. We will consider it as the field of ‘replacement, repair and regeneration’ of tissues or deficient organs. Advanced therapies such as gene therapy, somatic cell therapy and human tissue engineering are part of RM. Like any new technologies, the development of RM is balanced between opportunities and uncertainties, hope and hype, risk and benefits.

The field of RM has enormous potential and existing advances are being made. Nevertheless, numerous concerns arise concerning:

- Appropriate regulatory processes and new regulation for ‘combination products’ (living cell and scaffold for example), etc.
- Risk assessment and safety standards for the donation, testing, procurement, processing, storage, distribution and preservation of tissue and cells, (pure material, toxicology of the biomaterial, contamination, diffusion in the body), etc.
- Complexity of the issues and multidisciplinary science (how to go beyond the cultural divide between clinicians and scientists), communication skills (e.g. converging technologies), etc.
- Links between academic research and industries, competitiveness, intellectual property etc..
- Ethical issues e.g. consent, ownership, animal material, traceability of donors, surveillance of recipients, visions about ageless bodies, boundaries between therapy and enhancement etc.

This list is not an exhaustive one.

As has been learned with high profile controversies

over BSE, GM crops, public attitudes play a crucial role in the realization of new technological advances. Our societies depend on science and

technologies, the public awareness of the dangers and possibilities continues to increase. There is a clear mistrust in institution concerning the governance of technologies. Nevertheless, risk assessment should not constitute the only issues of the development of RM. Scientific community has the challenge today to listen and value the public knowledge. In biomedical research, concerned public such as Voluntary Health Organizations (like patient groups) can contribute by their personal experience of the disease to the development of the research and the clinical introduction. Innovation processes concerning RM must be opened at an early stage. RM development offers the challenge to integrate social and ethical reflections into the process of technology design in order to contribute to further developments in this promising field.

The upstream nature of RM gives an opportunity to generate a constructive debate about the future of these advanced therapies. The most effective models of care need to be developed. Upstream engagement, transparency, accountability, openness and confidence building will contribute to a governance from ‘bench to beside’.

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