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Regenerative medicine: basic and clinical research

The growth of stem-cell based therapies originated from the successful use of bone marrow transplantation, dating from 1968. In the following years success in the use of human stem cells [hSC] for transplantation in hematological malignancies has opened a window for their larger use in the therapy of degenerative diseases or of tissue injury, ranging from Parkinson's to heart disease, from diabetes to liver or kidney failure. The use of embryonic, pluripotent - or adult, multipotent - stem cells for growing cells/tissues *in vitro* for clinical regenerative medicine has also been proposed.

In this field, attention has focused on plasticity and transdifferentiation, which are interesting characteristics of stem cells [SC], with the possibility of allowing the localisation of SC to a specialized tissue by using appropriate conditions *in vitro*. Nevertheless the question of the stability of such commitment when the cells are injected or locally transplanted remains unanswered.

Substantial ethical questions have been raised as a result of these scientific achievements in regenerative medicine. Assuming that stem cells (SC) do have the potential to regenerate non-dividing human tissues, then more ambitious therapies using SC to target major disorders are in prospect. This makes the present time crucial for achieving this science progress. The constraints and difficulties are the result of conflicts between personal and group beliefs on the one hand and individual needs and hopes on the other.

A wide public discussion on policy in this area should be stimulated; and professional societies and trade associations should adopt both scientific and ethical safeguards and high standards of proficiency. Good scientific investigation is a driving force for new therapies. There is a moral imperative to foster medical advances and new clinical interventions using SC but these need also to respect the inviolability of human dignity and carefully to ponder potential ethical violations.

The European Federation of the National Academies of Medicine dedicated two Conferences to the scientific, practical and bioethical aspects of stem cell therapy, the latter being held in Rome, 11-12 May, 2007.

A group of experts in various areas of stem cell research, in biomedical application and in patient advocacy were invited to consultative meetings held under the auspices **EMBO** (European Molecular Biology Organization) on 19 April 2006 (EMBO 2006. Stem Cell Research. Status, prospects and

prerequisites), and **FEAM** (Rome, May 2007). Their final recommendations are given below:

In order that stem cell research and development in Europe stand the maximum reasonable chance of fulfilling their potential for advancing health-care, the biological sciences and the economy should be integrated:

- The prospective value of stem cell research in benefiting healthcare, knowledge production and the economy should be publicly recognised. Human stem cell research should be integrated into the mainstream of biomedical research, including disease modeling, study of cellular degenerative processes, development of pharmaceutical and toxicological screening platforms, and regenerative therapy.

- Research on both adult and embryonic stem cells, being highly complementary, should be fully supported; so too should research into understanding the reprogramming of the nucleus brought about by somatic cell nuclear transfer (SCNT), cell fusion and other techniques.

- Communication and professional education on stem cell research and applications should be promoted with active participation of scientists and clinicians along with ethicists, regulators and patient group representatives.

- Intellectual property relating to the utilisation of human ES cells and cell lines after their derivation from the embryo should be patentable in order to encourage the necessary industry involvement in the translation of stem cell research into clinical applications.

- Steps before clinical applications should include the evaluation of efficacy both in rodents and large animals (i.e. sheep, pigs).

- Regulations relating to stem cell research and applications should be clarified and harmonised, and wherever possible legislative obstacles to free international collaboration between scientists removed.

- Care should be taken that regulatory requirements are not excessively burdensome and do not present an unreasonable financial and/or bureaucratic barrier to clinical applications, as currently threatens.

- Efficacy measures and standard operating procedures for clinical use of stem cells should be developed. In establishing clinical practices, efficacy measures should be accorded at least as much significance as that of safety controls (i.e. risk of tumor development).

- Stem cell banks with high levels of quality assurance should be encouraged and international access by scientists and industry facilitated.

- Greater harmonisation and interlinking of clinical trials and their results across Europe should be promoted in order to facilitate cross-border studies and evaluation of all cell therapies (including, but not limited to stem cell therapies). Such an initiative should be for the benefit of all citizens and underpinned by public funding.

- Investments should be made in technology development to enable large-scale processing of stem cells for applications in pharmaceutical screening, toxicological testing, and cell transplantation.

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