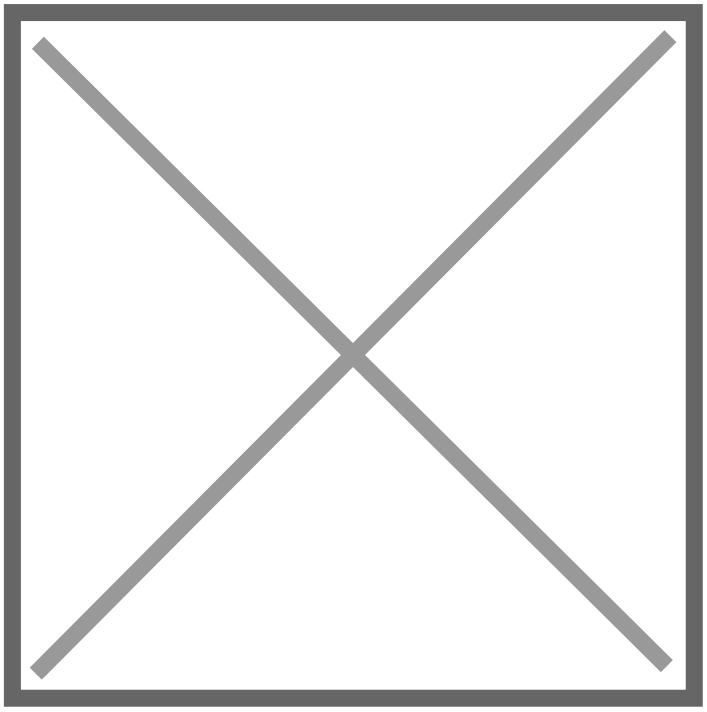
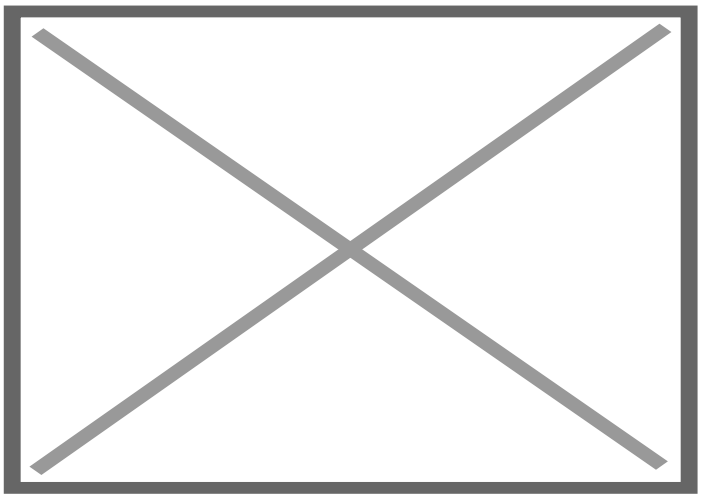
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Stem cell research needs regulatory pathway

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A well-defined regulatory pathway and guidelines are needed to carry forward stem cell research and to bring out promising stem cell therapy



Six-year-old Harshita, who was suffering from a genetic disease Ã¢â?¬â?? thalassemia major Ã¢â?¬â?? got a new lease of life following a successful stem cell transplant in New Delhi. Similarly, millions of people suffering from different diseases such as diabetes; cardiovascular disorders; neurological disorders; burns and wounds; osteoarthritis; osteoporosis; bone, cartilage and liver disorders; congenital abnormalities; and neoplasms, will get the benefits from stem cell therapies.

India is one of the few countries in the world pursuing stem cell research. But regenerative medicine, comprising stem cell therapies and tissue engineered products, has a long way to go. Commenting on the prospects of stem cell therapy, Mr KV Subramaniam, president and CEO, Reliance Life Sciences, says, Ã¢â?¬Å?In India, about 164 million patients Ã¢â?¬â?? suffering from diabetes, cardiovascular disorders, neurological disorders, burns and wounds, osteoarthritis, osteoporosis, bone, cartilage (joints & replacements), liver disorders, congenital abnormalities and neoplasms Ã¢â?¬â?? will benefit from stem cell therapies by the end of 2011. Stem cell therapies are proved to be effective for ocular, cardiovascular, and neurological disorders. With growing interest of private companies in this domain and support from the government bodies, stem cell therapy holds great potential to emerge as the promising therapy.Ã¢â?¬?

Ã¢â?¬Å?India shows more interest in stem cell research. Over 40 institutions, hospitals and companies are involved in stem cell research in the country. Till date, more than 90 programs have been implemented on various aspects of embryonic, iPS and adult stem cells. A few human embryonic stem cellÂ (ESC) lines have been generated in some of the institutions and are deposited in UK Stem Cell Bank and National Center for Cell Science, Pune. These cell lines are being used by the national and international researchers for research purpose,Ã¢â?¬? adds, Dr Alka Sharma, joint director, Department of Biotechnology, Government of India. Promoting stem cell research is one of her focus areas.

Current Scenario

According to reports, LV Prasad Eye Institute from Hyderabad has treated 600 corneal epithelium cases using stem cells, with 80 percent success rate. All India Institute of Medical Sciences (AIIMS), New Delhi; National Institute for Research in Reproductive Health (NIRRH), Mumbai; National Center for Cell Science, Pune; Center for Cellular and Molecular Biology,

Hyderabad; National Center for Biological Sciences (NCBS), Bangalore; and Sankara Nethralaya, Chennai; are the other institutes which are working on stem cells. Most of these institutes focus on regeneration of damaged muscles as a result of heart attack, stroke or cornea damage. While companies like Reliance Life Sciences, Cryobanks International India, CordLife and LifeCell have created facilities to store stem cells from umbilical cord.

Ã¢â?¬Å?Reliance Life Sciences has launched the first commercially available autologous limbal stem cell therapy, ReliNethra, for patients suffering from unilateral corneal blindness. Recently, we launched ReliHeal Ã¢â?¬â?? G (biopolymeric hydrogel wound management product) that promotes migration of new epidermal cells across the wound surface and is beneficial for early wound healing. We have also completed clinical trials using mesenchymal stem cells derived from the patient's bone marrow for myocardial infarction and we are carrying out clinical trials for application of stem cell-based therapies for stable vitiligo, non-healing diabetic ulcers, Parkinson's disease spinal cord injury and autologous stem cell conjuctival graft,Ã¢â?¬? says Mr Subramaniam.

Nichi-In Center for Regenerative Medicine (NCRM) is one of the few companies that is working on corneal epithelial stem cells. Apart from corneal stem cells, NCRM focuses on in vitro expansion of bone marrow and cord blood derived hematopoietic stem cells, which is expected to be a boon for leukemia patients.

Ã¢â?¬Å?We mainly focus on degenerative diseases and have worked on osteoarthritis, spinal chord injury, for which trials have been done on eight patients and no side-effects were identified. In coordination with Dr KR Suresh, head of the department and consultant, Vascular Surgeon, Bhagwan Mahaveer Jain Hospital, Bangalore, we have started working on the treatment for critical limb vascular ischemia since 2005 and the phase I trials have been successfully completed and the study results were published in the Journal of Vascular Surgery in 2009. We are planning to extend the study to phase II. Nearly 70-80 patients with critical limb vascular ischemia have been treated so far and in last one year, we have treated 25 patients with osteoarthritis and 15 patients with chronic renal failure,Ã¢â?¬? says Mr Gururaj Rao, research director, International Stemcell Services, Bangalore, which offers stem cell banking for regenerative medicine facilities including stem cell therapies, banking, expansion and differentiation.

India Market

Even though the stem cell research has emerged as a new branch of therapy with many institutes showing interest, it still remains a controversial topic amongst the public. And the main challenges faced are the lack of expertise, infrastructure, interdisciplinary network of researchers and clinicians for theme-based research, well-defined basic research leading to clinical/translational research and appropriate regulatory mechanisms.

Ã¢â?¬Å?The issues related to ethics are focused on embryonic stem cells. No ethical issues were raised against iPS cells, but it might take another decade or two for iPS cells to reach the bedside. We have been working on adult stem cells, where the issues are mainly scientific rather than ethics. When the safety and efficacy are proved, it will become a routine therapy, as there is no issue related to misusing embryos,Ã¢â?¬? says Mr Samuel JK Abraham, director, Nichi-In Center for Regenerative Medicine (NCRM), which carries out research, training and clinical applications-protocol development in regenerative medicine.

Ã¢â?¬Å?No stem cells are universal that could address all the diseases. Bone marrow-derived stem cells may be good for few diseases but may not be good for others. Therefore, it is necessary to look and investigate new stem cells present in the human body that may be good and have certain therapeutics potential. But, the major hurdle faced is that there is no proven data that the stem cells are totally safe. Until we finish the clinical trial, it is not recommended to use stem cells for any diseases as therapy. People have little knowledge about scientific methods, overall process of science and their usefulness. Hence, the probability of people getting cheated are on high,Ã¢â?¬? says Dr Satish Totey, president, Advanced Neuro-Science Allies (ANSA), which focuses on stem cell research and therapy primarily in neurological disorders and other diseases.

Ã¢â?¬Å?Many hospitals in India do not follow quality control since the stem cell injections are for parental use. Instead of creating controversy over stem cell therapy, regulatory bodies or committees should control very basic rule of Indian FDA that any injectable solution in India need certain facility and parameter and quality testing before injecting it in human or animal. Except bone marrow transplantation for cancer patient, no other therapies are yet proven and are a standard medical practice,Ã¢â?¬? adds Dr Totey.

The lack of awareness is one of the serious problems faced in stem cell research. With no proper trials or follow up the treatment is reaching the public. Many researchers and practitioners are aiming at the commercial aspect of it, thereby harming the human society.

Ã¢â?¬Å?If proper awareness is given, people would encourage the new treatment. But, the only problem is that there is no

regulation in this field. We have many doctors in New Delhi, who claim to treat many diseases using stem cell therapy and they charge $7,500-$8,500 (3.5-4 lakh) per injection. This is a grave issue which needs to be addressed. Even without proper approval by any regulatory body, practitioners are indulging in various treatments using stem cells, which is not at all safe. The rules are mainly followed to meet the pharmaceuticals requirements. Like pharmaceuticals, one cannot approve stem cells on the basis of dose-response ratio. Hence, the drug control rules are not applicable when it come to stem cell therapy,Ã¢â?¬? says Mr Rao.

Sharing his thoughts on the issues before the stem cell research community, Dr Totey says, Ã¢â?¬Å?There is no proper policy in this country and currently it is free for all kind of situation. Funding is very low and therefore the available funding cannot address all the potential ideas and good science. Funding is mainly alloted for low risk project, which is a barrier for innovation. R&D is not for public use. It is largely accessible to only select group of people. There are only a few clinical trials which get approval from Drug Controller General of India (DCGI). The central government should have clear mandate about their requirement rather than allocating funds for free. They should look for priorities and identify potential problem diseases in India. They should identify groups and expertise and give them a timeline to bring this product in the market for the needy patients. After which they can give these therapies to industry at a low cost so that the patients get benefited.Ã¢â?¬?

Considering the huge potential for stem cell market, many global players are eying India. Ã¢â?¬Å?The government authorities should provide fund for clinical trials instead of basic research. Encouraging basic research is needed but doing just basic research won't help. Practically, clinical trials should be encouraged to make the research more effective. If India does not move ahead with trials then foreign players will soon emerge ahead in the market,Ã¢â?¬? says Mr Rao.

With a lot of vulnerable factors attached to this therapy, the role of authorities and need for regulation is of much importance. A well-defined regulatory pathway and guidelines are needed to carry forward the stem cell research.

Organizations working on stem cells
Reliance Life Science, Mumbai
Stemputics, Bangalore
International Stemcell Services, Bangalore
Advanced Neuro-Science Allies (ANSA), Bangalore
Nichi-In Center for Regenerative Medicine (NCRM), Chennai
All India Institute of Medical Sciences (AIIMS), New Delhi
National Institute for Research in Reproductive Health (NIRRH), Mumbai
National Center for Cell Science, Pune
LV Prasad Eye Institute, Hyderabad
Center for Cellular and Molecular Biology, Hyderabad
National Center for Biological Sciences (NCBS), Bangalore
Sankara Nethralaya, Chennai
Bhagwan Mahaveer Jain Hospital (Jivas), Bangalore
Indian Institute of Science (IISc), Bangalore
National Brain Research Center (NBRC), Haryana
Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad
Nizam's Institute of Medical Sciences, Hyderabad
Tata Institute of Fundamental Research (TIFR), Mumbai
National Institute of Mental Health and Neuro Sciences (NIMHANS), Bangalore
Post Graduate Institute of Medical Sciences (PGIMER), Chandigarh
National Institute of Immunohaematology (IIH), Mumbai
LifeCell, Chennai
Pacific Stem Cells, Hyderabad
Cryobanks International India, Gurgaon
CordLife, Kolkata

Even when controversies are on a high, the Department of Biotechnology (DBT), Government of India, has allocated $650,000 (3 crore) in the last five years towards basic and applied research in stem cell technology.

The Indian Council of Medical Research and the DBT had already announced the guidelines for stem cell research and therapy in 2007, but India is yet to formulate norms for stem cell banking and storage procedures. The stem cell banking in India is yet to come under a regulatory framework. Moreover, Stem cell continues to be a promising field, which will rise to new levels in the coming years.

Quotes:

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Ã¢â?¬â?? Mr KV Subramaniam, president and CEO, Reliance Life Sciences

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Clinical trials should be encouraged to make stem cell research more effective. If India does not move ahead with trials then foreign players will soon emerge ahead in the market.
Ã¢â?¬â?? Dr S Gururaj A Rao, chairman & managing director, International Stem Cell Services



'Stem cell research is one of the thrust areas for DBT'

- Dr Alka Sharma, joint director, Department of Biotechnology, Ministry of Science and Technology, Government of India

QÂ Researchers have found new sources of stem cells such as corneal epithelium and bald scalps, what kind of support does DBT offers for such research?
Stem cell research is one of the thrust areas of the Department of Biotechnology (DBT). It is supporting proposals on various aspects of stem cells including discovery of new sources of stem cells, and their applications in animal models. Support for proposals on stem cells from small and large biotech companies is also being considered and will get implemented through public-private partnership schemes such as Small Business Innovative Initiative (SIBRI) and Biotechnology Industry Partnership Program (BIPP).

QÂ Last year, few meetings were organized by DBT to discuss the guidelines for stem cell research. What is the current status on these developments?
Draft guidelines for stem cell research in the country have been formulated jointly by the DBT and the Indian Council of Medical Research (ICMR). These two agencies are working in close collaboration. Region-wise public consultations were organized at four places in 2010. The public consultation for the central region (northern region) is in the pipeline. The recommendations will be finalized and implementation report will be completed after the public consultation in the central zone.

QÂ With many organizations targeting commercial profit from stem cell research/ therapy, what role can the government play as a regulator?
The guidelines for stem cell research have been formulated and the same have been submitted to the Ministry of Health and Family Welfare for further processing as a legislation. Once it is converted into an Act with penalty clauses, it will help in regulating medical applications and curbing misuse.

The DBT has constituted an independent Ã¢â?¬Å?Ethics Committee for Stem Cell ResearchÃ¢â?¬? to consider the proposal from ethics point of view. Each proposal cleared by the respective Institutional Ethics Committee (IEC) is being considered by the DBT's Ethics Committee before processing. Our processes for funding are very stringent. The ICMR has similar credible arrangement.

QÂ What are the measures taken by the DBT to step-up stem cell research in India?
As with all areas of biology, the limiting factor for stem cell research is the inadequate number of scientists who specialize in stem cells. DBT has initiated fellowship schemes such as Wellcome Trust Fellowship and Ramalingaswamy Fellowship for increasing the talent pool in the country.

The key components of our strategy are:

- Develop a skilled and brilliant pool of scientists in the area of stem cells
- Establish Center of Excellence in basic science institutes, medical institutes and selected animal institutes
- Operationalization of autonomous stem cell institute in Bangalore
- Organize world-class science meetings

- Send young people for overseas training
- Support public-private partnership research
- Establish global partnerships

Suchithra Pillai in Bangalore