India's current development and regulation of the regenerative medicine sector

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Regenerative medicine in India: Trends and challenges in innovation and regulation

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India, like many other countries, has invested in advancing research and commercialisation of regenerative medicines through several initiatives. This has greatly helped advance India's regenerative medicine sector by increasing the number of institutes, companies and hospitals participating in research and therapy development. However, a loosely structured governing framework based on indefinite guidelines is in need of reform for India to fully harness and capitalise on its growing RM sector.

What questions & challenges are raised?

Just like many other countries, India has invested large amounts of resources into developing their regenerative medicine (RM) sector because of the promises it holds for transforming health care and generating commercial growth. Dr Shashank Tiwari and his colleagues have written a perspective outlining several initiatives India has put in place to grow the RM sector and discuss the government's regulation of this field. In addition to gives an overview of the current state of India's stem cell research and therapies, the perspective focuses on additional emerging sub-sectors of RM, such as gene therapy, biomaterials, and 3D bioprinting (designing and patterning cells using 3D printing technologies).

What insight & direction does this give for research policies?

Dr Tiwari and his colleagues remark that the government's active promotion of RM has made a clear impact in the advances and growth seen in India's academic and industrial progress. However, permissive government regulatory policies in the name of innovation also allow "controversial technologies" to flourish. Dr Tiwari and his colleagues advocate that for India to fully profit from the investment into RM, it must also create an effective regulatory framework to control how new innovations are being implemented into clinical and public use. This will entail addressing the sale and misrepresentation of unproven stem cell treatments by clinics, establishing better guidelines for 3D bioprinting and nanotechnologies, nationally addresses antibiotic resistance, creating policy cohesiveness across industry sectors and geographical regions, and ensuring that public investments into RM don't ultimately widen inequalities of healthcare access for the people of India.

What background and point are discussed?

DDr Tiwari and his colleagues discuss how several government initiatives have begun to promote growth in India's field of RM, including several of India's domestic manufacturing and business development programs, such as Make in India (2014) and Startup India (2016). In the case of stem cells, the Department of Biotechnology (DBT) has invested in basic stem cell research since 2001 and today claims that over 40 institutions, hospitals and industries are actively involved in research. The DBT has also created an independent research institute in 2009, called the Institute for Stem Cell Biology and Regenerative Medicine (inStem). This institute promotes networking, collaborative research and translational development of therapeutics between researchers, medical professionals, and businesses on a national and international level. India also has many hospitals developing stem cell treatments, such as L V Prasad Eye Institute, which developed the successful 'Simple Limbal Epithelial Transplantation' technique and is collaborating with the University of Sheffield (UK) to create biocompatible materials for transplants. Dr Tiwari and his colleagues note that many public and private hospitals in India engage in basic and clinical research. There are, however, an estimated 300 clinics in India offering various unproven stem cell treatments. Most of these clinics use adult stem cells, however one clinic, NuTech Mediword, sells highly controversial embryonic stem cell treatments. Umbilical cord blood bankings are also on the rise, but many say claims of their merits and medical uses are largely over-stated. Despite this, cord blood banks across India have rapidly multiplied to over 500 unregistered banks and only 14 registered and licensed banks.

Other areas of RM that Dr Tiwari and his colleagues comment on include gene therapy, where treatments focus on correcting genetic mutations linked to diseases. There are about ten laboratories and a few companies working on gene therapies, including one institutes involved in an international collaboration to address Hemophilia, a bleeding disorder that prevents blood from clotting. India also has a significant number of institutes contributing to tissue engineering and biomaterials research in RM, areas of research developing methods to build tissues and organs out of cells and biologically compatible materials. Some examples of Indian biomaterial include artificial vascular grafts for replacing blood vessels and synthetic bone material for bone grafts. The perspective references recently developed nanofiber scaffolds that also prevent infections from antibiotic-resistant bacteria to illustrate how RM innovations that limit bacterial infections could be another opportunity for growth in India. 3D bioprinting is seen by researchers in India as a potentially revolutionary health care advancement, opening opportunities for 'printing' cell-by-cell new skin tissue, bone and perhaps whole organs. Surgeons are already using 3D printing to make custom-designed metal implants and scientists can create cartilage replacements from mixtures of silk, stem cells and other factors.

Dr Tiwari and his colleagues note that there is a large contrast between India's policies, which have a cohesive logic to stimulate and link multiple sectors of the RM industry, and India's regulation policies, which are a patchwork of guidelines from several sub-sectors of RM. This year the India Council of Medical Research and the DBT issued new revised guidelines focusing primarily on stem cell research. The guidelines discourage clinical and therapeutic use of stem cells (excluding approved blood treatments and monitored clinical trials), but also contain a provision with ambiguous terminology that allows 'minimally manipulated' stem cells to be used in unapproved treatments. While some sectors, such as gene therapy, have dedicated guidelines, other areas, like nanomaterials and 3D bioprinting, only have vague guidelines or no regulations at all.