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Read these new rules before going in for a 'stem cell cure'

Med Panel Draft Also Lays Gene Editing Norms

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Mumbai: Considering the mushrooming of stem cell clinics offering "cures" for conditions ranging from diabetes to autism across the country, the Indian Council for Medical Research (ICMR) and the Department of Biotechnology (DBT) have come up with guidelines on who can conduct research in this sphere, when and how. Moreover, the draft, for the first time, provides guidelines for cutting-edge gene editing techniques.

Giving a three-page list of conditions for which stem cells can be offered, the draft omits conditions such as motor neuron disease, mental retardation or muscular dystrophy. It makes it clear that doctors should stick to their specialty. "Doctors cannot criss-cross areas of specialization," said ICMR deputy director general Dr Geeta Jotwani. "At present, there are orthopaedic surgeons who offer so-called stem cell therapy for neurological problems or vice-versa. We are now clearly saying that only clinicians with subject domain can offer clinical trials."

The 40-page draft is available on the ICMR and DBT's websites, and is open to public comments and concerns till July 31. "Stem cells have a lot of potential in disease management. Our last guidelines came out in 2013, but a lot has changed since then, making us feel the need to update our guidelines. We want to encourage people to do research in stem cells, but at the same time want to ensure nothing unethical is carried out," ICMR director general Dr Soumya Swaminathan told TOI.

On the mention of gene editing techniques, she said, "We want our researchers to take up work in this field. US researchers have been working on gene editing for cancer, HIV, etc, but we in India haven't yet come to that point. We have included CRISPR-Cas9 (gene editing tool) in the guidelines, but only for research in somatic (normal or non-reproductive) cells."

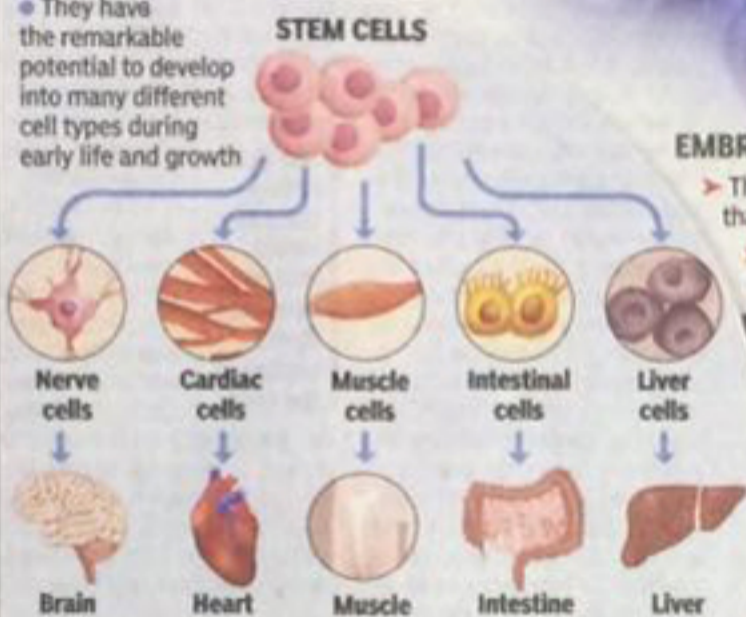
The guidelines mainly seek to curb malpractice. Dr Jotwani said stem cells are only offered as clinical trials in the West, but are offered as therapies in India. "We have received many complaints. Now on, all institutions carrying out research must register with the National Apex Committee for Stem Cell Research and Therapy."

A senior Mumbai doctor said, "An autologous stem cell extraction (using a person's

WHAT ARE STEM CELLS?

STEM CELLS ARE THE MASTER CELLS OF THE BODY

• They have the remarkable potential to develop into many different cell types during early life and growth



• When a stem cell divides, each new cell has the potential either to remain a stem cell or become another type of cell with a more specialized function, such as a muscle cell, a red blood cell, or a brain cell

• In many tissues, they serve as a sort of an internal repair system, dividing essentially without limit to replenish other cells

EMBRYONIC STEM CELLS

- These come from an embryo that is a few days old
- Can form virtually any type of cell in the body

Given the potential for their misuse, research into embryonic stem cells is highly restricted

ADULT STEM CELLS

- These are undifferentiated cells found in a tissue or organ after birth
- Have a restricted ability to produce different cell types

IS STEM CELL THERAPY BEING MISUSED IN INDIA?

Many doctors and clinics offer stem cell cure for several diseases, including diabetes, muscular dystrophy, motor neuron disease, spinal cord injury and autism

Experts say most of these treatments are still at the experimental stage across the world, but are being offered as cures in India

2 Patients and their families pay lakhs of rupees for one injection of stem cells

Experts say these treatments could not only be seen as financial exploitation, but could give rise to tumours due to the ability of stem cells to proliferate

STEM CELL INJECTION | An autologous stem cell injection involves using the person's own stem cells. These are collected in advance and returned at a later stage. They are used to replace stem cells that get damaged due to underlying disease



NEW GUIDELINES BY INDIAN COUNCIL FOR MEDICAL RESEARCH

Fresh guidelines by the ICMR provide a comprehensive framework for researchers, doctors and institutions to carry out research

➤ They specify medical conditions for which doctors can use stem cells

➤ State that genome modification, including gene

editing (for example by CRISPR-Cas9 technology) of stem cells, germ-line stem cells or gamete and human embryos, is restricted only to in-vitro studies (studies done in controlled environment outside the body of a living organism)

➤ Link doctor's specialty with treatment. Lay down

the ethical framework to be followed for research

➤ Lay down composition of various committees at national or institution level

➤ Give out methods to collect stem cells and their storage

➤ Prohibit doctors and clinics from indulging in publicity or advertisement of therapies

own stem cells) and processing doesn't take the sort of money—almost Rs 10 lakh—being charged from patients. This kind of exploitation should stop"

The guidelines also state that stem cell research can only be carried out in laboratories

and institutions that comply with GLP (good laboratory practice) and GMP (good manufacturing practice).

Incidentally, ICMR had asked doctors of the 500-odd clinics doing stem cell work in India to report progress. None did within the December 2016

deadline.

"There is no conclusive work on stem cells to prove that they can help patients with conditions like Duchenne muscular dystrophy, mental retardation or autism," said Dr Vrajesh Udani, head of paediatric neurology, Hinduja Hospital.