

Q.1. What is the status of Stem Cell treatment in India as well globally?

In India as well as globally, only blood stem cells from bone marrow to treat blood cancers and different blood disorders are permitted.

The clinical use in any other disease or use of any stem cells other than these is still in research stage.

Q.2. At present for which diseases, stem cell therapy is available?

- ❖ Though stem cell therapies are being touted as a panacea for all ills, but at this point in time, only the blood forming (hematopoietic) stem cells from bone marrow or umbilical (nadi) cord blood are routinely used to treat blood cancers and different blood disorders. This is known as bone marrow transplant (BMT) or hematopoietic stem cell transplant (HSCT).
- ❖ For other diseases, studies are being conducted to find if stem cells can be helpful in curing these diseases.

Q.3. Is stem cell treatment available in India for diseases other than BMT/HSCT for some blood cancers and blood disorders? Are there Government Hospitals where stem cell therapy is being provided?

- ❖ No. At present, stem cell therapy other than BMT/HSCT for conditions as listed in the NGSCR 2017 is neither available nor permissible.
- ❖ No Government hospital offers stem cell therapy for unproven conditions.
- ❖ In case a clinical study is ongoing, patients may avail the treatment as part of the trial if they fit into the requirements of that trial.

Q.4. Can hospitals offer Stem Cell Treatment for different ailments?

No. As per NGSR 2017, it is considered unethical and a malpractice and is violation of the existing National Guidelines for Stem Cell Research, a clinician/hospital claims to commercially offer stem cell therapy as a cure for any disease.

Q.5. There are several clinics that offer stem cell based therapies saying they have done clinical studies/trials and/or provide testimonies of patients who have been cured from the stem cell treatment done at their clinic. How valid are such trials/studies/testimonies?

- ❖ It must be kept in mind that best studies/trials are 'randomized controlled trials' which are considered level I evidence and policy decisions are mostly based on meta analysis of the level I evidence studies.
- ❖ Claims/testimonies/case studies are individual opinions/single case observations that are considered weak evidences as they lack proper design, have bias and do not provide statistically significant results.

Q.6. There are several clinicians/hospitals/entities advertising and offering stem cell therapy for many incurable diseases through electronic and print medium. What actions can be taken against such advertisements?

It may be noted that actions can be taken against the erring clinicians/entities as per the following existing rules and regulations.

- a. The advertising and publicity through any mode by clinicians is not permitted as per Chapter 6 of the Indian Medical Council (Professional Conduct, Etiquettes and Ethics) Regulation. It is mandated that the MCI and Medical Councils of respective state should initiate action on the erring clinicians for violation of code of ethics prescribed by it either taking *suo moto* cognizance or acting on any complaint received by them.
(Available at: <https://www.mciindia.org/documents/rulesAndRegulations/Ethics%20Regulations2002.pdf>)
- b. The Drugs and Magical Remedies (The Objectionable Advertisements) Act- 1954 –prohibits misleading advertisements relating to drugs and magical remedies. DGHS and relevant state authorities are mandated to take necessary action for violation of this act. (Available at: <http://lawmin.nic.in/ld/P-ACT/1954/A1954-21.pdf>).
- c. The advertisement of treatment of several diseases as listed in Schedule J of Drugs and Cosmetics Act, 1940 and rules therein (*Annexure VII*) is not permissible. Hence publicity claiming available cure for these conditions using stem cells and its derivatives is prohibited. CDSCO, DGHS and relevant state authorities are mandated to take necessary action for violation of this act.
- d. No advertisement which violates the code for self regulation in advertising, as adopted by the Advertising Standards Council of India (ASCI), Mumbai for public exhibition, from time to time, shall be published. (Available at: https://ascionline.org/images/pdf/code_book.pdf). The complaints can be made online at the following weblink of ASCI <https://ascionline.org/index.php/lodge-ur-complaints.html>

Q.7. Which agencies can be approached to report unethical practices of clinicians/hospitals/entities that are offering unproven Stem Cell Treatments?

If you come across any hospital/ doctor/ clinic offering un proven therapy and also charging for the same OR have

been charged by any hospital/doctor/clinic for stem cell therapy, you can submit the complaints with details to following agencies:

- ❖ *State Medical Council*
- ❖ *Ethics Committee Medical Council of India*
- ❖ *State Indian Medical Association*
- ❖ *State Office of Central Drug Standards Control Organization*
- ❖ *Indian Council of Medical Research.*

For further information on the stem cell treatments across the globe, please visit the following sites:

<http://www.closerlookatstemcells.org/stem-cells-and-medicine/nine-things-to-know-about-stem-cell-treatments>

<http://www.closerlookatstemcells.org/stem-cells-and-medicine/stem-cell-treatments-what-to-ask>