



Public briefing:

PATIENT NEEDS AND STEM CELL RESEARCH IN INDIA

Key Issues in General:

- **Patients have diverse needs:** Some are willing to try any available therapy to get better at any price, while others are willing to wait for officially approved therapy
- **It is not clear to what extent therapies are safe/efficacious** as therapeutic effects are understood by scientists differently. Some clinics are prepared to provide experimental therapies in the hope they work; others only will do this after clinical evidence is obtained.
- In sum: **Scientists and patients do not agree on how experimental stem cell therapy should be regulated.**

Important concerns for patients:

- **Access to information:** Patients find it difficult to obtain information (a) on the nature and treatment options on the disease, (b) on what kind of research is being done in the field, (c) on the whereabouts of possible therapies; and, (d) on clinical trials: where is it going on and whether and how to participate in it.
- **Affordability:** The cost of stem cell therapy (experimental or otherwise) is high; insurance coverage for general healthcare is low and regenerative medicine treatments are not covered under any health insurance.
- **Ensuring consent:** (a) the patient should decide what is best for him/her, and (b) written informed consent should be taken in a language understood by the patient (possibly videographed).
- **Wider access to healthcare and support:** Needs other than stem cell therapy, such as improved general healthcare, rehabilitation programmes, better infrastructure such as wheelchairs, lifts, provision of catheters, alternative and suitable employment

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opportunities, more basic research on several disease conditions, family support, more public awareness and education on issues such as road safety are also important.

Recommendations: Steps to be taken towards a general consensus

- **Set up a network for patient/ consumer groups to represent patient interests with the Ministry of Science and Technology's Department of Biotechnology (DBT) and the Indian Council on Medical Research (ICMR).** Patients need greater involvement in clinical trials and decision-making about patient needs
- **Access for patients to experimental stem cell therapy should take place in controlled settings**, whether clinical trials or 'pay-to-participate schemes'. *If* the latter were to be allowed, then basic safety and efficacy standards would need to be in place, scientific protocols followed, and maximum fees agreed.
- **Policies of benefit sharing are needed.** E.g., to link the availability of new therapies to insurance coverage, or access to drugs.
- **Information about stem cell therapy needs to be accessible to patients** in local languages or through a national information portal (hotline) for patients and their caregivers
- **Governance mechanisms need to be transparent:** Clarity is needed about which government and medical bodies are responsible for oversight and medical malpractice and what the appropriate procedures are for filing complaints.

Need for a public sector intermediary agency:

- An intermediary agency is needed to coordinate the diverse needs of patients, scientists, medical professionals in how regulation takes place.
- Such an agency could mediate *inter alia* between scientists and patients, coordinate patient needs with public health and science policies and set priorities in terms of how to best cater for patient needs.
- Such an agency would devise ways to effectively make available information on therapies for patients, initiate systems of benefit sharing and seek ways to make the most promising therapies available to the patients that need them.
- The agency would collect data on the great diversity of patient experiences and the diversity of scientists' views of what are promising therapies.
- Such a non-commercial intermediary agency providing these services would be located in the public sector but work in liaison with industry and commercial institutions.



For further information see:

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