EDITORIAL

Issue of Transparency in Stem Cell Therapy

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Stem cells are undifferentiated cells that have the potential to transform into various cell types in the body. They have a distinct character of renewing themselves by cell division. There are two types of stem cells, the embryonic stem cells and the adult or somatic stem cells. In 2006, a new type of stem cell, the induced pluripotent stem cell, was successfully developed. Stem cells can become cells with organ specific functions. They also have the capability to repair and replace those cells that are damaged or diseased.[1,2]

Stem cell research is progressing at a fast pace. The potential of stem cells is increasingly being explored and technologies are being developed to use them for various genetic, inborn and acquired diseases. It is important at this point in time to make a clear distinction between clinical trials and medical treatments. These terminologies are not interchangeable.[3] While, medical treatments are safe to be employed for various diseases, trials are experiments and cannot be recommended as a standard of care treatment, unless approved to be used for general public by an accrediting authority such as Food and Drug Administration (FDA) of United States. Stem cell research is still under trial and only few treatments, based upon stem cells, are approved by FDA, though various claims have been made of its use both in experimental research reports and commercial advertisements.[4,5]

Research on adult stem cells has not generated much debate as compared to embryonic stem cells, but in recent years a great misconception has been generated in various quarters as to the safety and usefulness of adult stem cells for general use in clinical set-up. The FDA in United States, that regulates stem cells and consider them as drugs (therapeutic agents), has issued directives from time to time about safety of stem cell therapy. Stem cells of bone marrow and blood origin have been used in the treatment of some blood cancers and other blood disorders. Stem cells from another source, the umbilical cord of the new born is a recent addition to harvesting of stem cells. FDA regulates cord blood collection which is allowed for research purposes and its possible use as a therapy in human subjects.[6] Special blood banks, the Cord Blood Banks are licensed to collect umbilical cord blood following delivery. Strict regulations are observed in this regard.

In November 2011, FDA approved Hemacord, a commercial product which was the first licensed haematopoietic progenitor cells-cord (HPC-C) cell allowed to be used as therapy. This product is of human cord blood origin and therefore, considered a biological product. A long-list of possible side effects are also mentioned including graft versus host disease, graft failure, engraftment syndrome, immunological reactions and even fatality following its use.[7] Recently, an advertisement about umbilical cord blood bank facility in Pakistan appeared on Internet. It is also of interest to note that a medical university hospital in Karachi is also offering this facility and is conducting research on this subject. It is heartening to note that such research activities are taking place in our country but are these researches monitored by authorities? This is an area of concern. In Pakistan, no Registry exists where clinical trials can be registered. In the absence of such Registry and lack of rules and regulations, it will not be a surprise if some researchers claim development of a new treatment and good outcome following its use.[8]

Umbilical blood is a biological sample. It is the property of an individual. There are specific guidelines to be followed for their use in research. At present, neither are the ethical review committees available in all institutions of Pakistan nor our patients / public aware of the potential abuse of their biological samples. It is also not known if cord blood collected shall remain in Pakistan or be sent abroad for research / treatment purposes. Incidences have been reported, where umbilical blood samples collected at birth were used by researchers without the knowledge of the individuals.[9] Claims have also been made that by storing umbilical blood at birth, same shall be available in future for the person in case he/she develops disease where stem cells may have the role in the treatment like haematological malignancies. It is not clear as to how many individuals shall benefit from this and how much money will be spent in storage of these samples for future use. So the cost effectiveness of storage is another consideration.

Individuals suffering from diseases for which treatment is not available or not successful are often exploited by advertisements that stem cell therapy can cure them. Such conditions include paralysis due to spinal cord injury, myocardial infarction, Alzheimer's disease etc. This vulnerable group is often the victim of such malicious claims. Stem cell tourism is increasingly

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recognized, where patients travel to countries like China, Costa Rica, India, Singapore, South Korea and many others, to receive unproven stem cell therapy. This poses risks of not only the transmission of communicable diseases, but also of potential hazards related to stem cells themselves that include development of cancers and even death.[10,11]

Research is an integral part of scientific development. However, while pursuing discovery of new treatment modalities, standard operating procedure must be followed. Though ultimate beneficiary shall be patient population and industry as well, the ethics of research must not be violated. Transparency must be ensured at each and every step and nothing must be hidden from the public. All conflict of interests must be declared and distinction must be made between trial and treatment. All research must be peer reviewed with explicit methodology and documentation of side effects. A genuine informed consent must be obtained from research participants. All potential risks must be told to them rather than describing only the potential benefits of the therapy.[12] Only then the outcome of research shall be fruitful to the human race.

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