

Regulate Cord Blood Banks

- Suman Sahai

India is emerging as one of the leading centres for cord blood banks, which can provide stem cells for regenerative medicine. These are essentially blood banks, which collect, process and store umbilical cord blood for transplants. Umbilical cord blood is blood from the placenta and is rich in stem cells. Cord blood is collected after the umbilical cord has been detached from the newborn, and utilised as a source of stem cells for transplantation. Umbilical cord blood is playing an increasingly important role in the treatment of leukemia and other life-threatening diseases. More easily accessed than embryonic stem cells and more flexible than adult stem cells, the stem cells recovered from the blood in the umbilical cord provide a non-controversial treatment option for a range of diseases.

India opened its first cord blood bank in Chennai in 2004, with a drive to collect and store umbilical cord blood in a private bank. Twelve pregnant women registered with the private bank called Life Cell to store their baby's umbilical cord blood. LifeCell guarantees that the stem cells gained from the cord blood will be stored for 21 years at a cost ranging from Rs 30,000 to Rs 60,000. Since then, several other cord blood banks have come up in India, many with international collaboration, all with similar price tags. Large private banks like Life Cell, TIFR (Tata Institute of Fundamental Research) and Cryostem Karnataka Pvt Ltd are entering the international market and will bid for international funds to conduct research on embryonal stem cells. All three are recognised by the National Institute of Health (NIH) in the US, which paves the way for their international operations.

India is seen a desirable destination for setting up cord blood banks because of its large, young population of ethnically and genetically diverse potential donors. The use of stem cell therapy in a number of life threatening diseases promises to be a money spinner in the medical sector. The cord blood storage market is currently estimated to be about US\$2 billion, with every prospect of substantial growth in the coming years. As in all other fields of medical treatment, the question here is also that of regulation and equitable use. So far, the only countries that have put in place regulations for stem cell research and development, are the US, China, Singapore, Israel, Belgium and UK.

India has prepared some guidelines but these are not official yet. Broadly, these guidelines allow work on cord blood, adult and embryonic stem cells but prohibit the use of adult stem cells to create a new zygote, in other words, a new embryo. A nodal body, the National Apex Committee for Stem Cell Research and Therapy, has been proposed where all researchers and institutions working on stem cells will have to register. Permission from this body will be required for all applications of stem cells, including research. All stem cell lines that have been established, along with the source of the original material, will also have to be registered with the apex body. Given

its potential for use and abuse, a regulatory system governing the use of cord blood stem cells will have to be vigilant in ensuring that not just private players but also public banks are set up for cord blood, which can be accessed by the public.

New technologies cannot be such that they shut out the poor because they are expensive and unaffordable. Even with stringent regulations, there are outstanding ethical and practical dilemmas associated with this promising but radical technology. At the simplest level, is the question of the facilities themselves: how reliable is the infrastructure for reliable and safe storage; what will be the accepted methodologies of processing and transport of such materials; and, how will the integrity of the stem cells be ensured. There is no law yet, for instance, to govern ownership of tissues like the umbilical cord or the stem cell line generated from the cord blood. What kind of intellectual property regime will we allow on material, which belongs to individuals but has been processed by researchers and institutions? What kind of liability laws will govern this field if things go wrong and accidents happen? How will awareness be created among the public about the availability of this facility, so that its use does not remain restricted to only those who can afford private cord blood banks. Necessary policy will need to be formulated to ensure a sufficient number of public cord blood banks and investment must be made to ensure that the public, specially the poor, can also bring their babies for cord blood storage in the hope of treating future diseases.