



## INDIAN COUNCIL OF MEDICAL RESEARCH

New Delhi - 110029

### FAQs on cord blood banking

**1. Is umbilical cord blood (UCB) banking service covered under any guidelines/norms in the country?**

Umbilical Cord Blood banks (UCB) are permitted only under license and monitoring by the Central Drug Standards Controlling Organization (CDSCO). The Cord Blood Banks have to comply with the Drugs and Cosmetics (3rd Amendment) Rules, Gazette Notification No. GSR 899(E) dated 27/12/2011 for collection, processing, testing, storage, banking, and release of stored units.

(Available at: <http://cdsco.nic.in/html/GSR%20899.pdf>).

**2. How can one know about the CDSCO licensed banking services available in the country?**

The CDSCO website provides the list of all the licensed UCB banks in the country.

<http://www.cdsco.nic.in/writereaddata/Umbilical-Cord-Blood-Banks-India.pdf>

**3. Can banks store tissues other than UCB as a source of stem cells?**

No. At present only banking of UCB is permitted. Hence the storage or banking of any other tissue for example dental pulp, cord tissue, Wharton jelly etc is not permitted.

**4. Is there any scientific credibility to storing UCB for future self use?**

Several international bodies such as American Academy of Pediatrician, American Society for Blood and Marrow Transplant, Royal College of Obstetricians and Gynecologists, American College of Obstetrics and Gynecology, American Medical Association, European Group on Ethics in Science and New Technologies etc. do not recommend routine private banking for future self use. The reasons being:

The likelihood of the stored blood being used for HSCT is very small, probably as low as 0.005 to 0.04% in the first 20 yrs of life.

Stem cell transplant using an individual's own cord blood (autologous transplant) cannot be recommended for genetic disorders.

The private banking is suggested in cases where there is a relative/sibling with a condition or there is a family history of malignant or genetic conditions that can be treated with HSC transplantation. Moreover, banking for allogeneic transplant is recommended when there are shared HLA antigens between parents.

**5. What types of people are choosing to have the UCB banked?**

Initially, the banking started in the metro urban class people who could afford the cost of banking. Now with intensive advertisement by the cord blood banks, the upper middle and middle class is getting aware about banking and opting for it even in smaller cities and towns.

**6. What are the concerns regarding the advertisements by cord blood banks?**

The misleading and luring advertisement by private cord blood banks is an area of major concern. Such ads often involve celebrities as their brand ambassador's prompting storage as status symbol because celebrities are doing the same. The expectant parents venture under the influence of such advertisement without knowledge about possible self or family use. They are

emotionally as well as economically burdened to store the child's UCB as a form of biological insurance for future use. The advertisements are misleading the public into believing that the child's own UCB can protect it from the 80 different medical conditions and this statement is not scientifically supported. Another propaganda made on the websites of the private banks is the utility of stem cells in several incurable diseases (unproven conditions) through blogs and testimonials of patients and doctors. This again is a catch 22 situation for the expectant parents who are made to think that they are depriving the child of future panacea by not storing the UCB. Moreover, banks also indulge in practices like following up the expectant mother and healthcare professionals offering them incentives to for availing the facilities.

**7. What are the general concerns regarding banking practices/ Are people being taken advantage of?**

Yes. As mentioned above/Parents are not given accurate information regarding utility of stored tissue. There is no clarity if the tissues stored are viable, as there have been several instances when the tissues were asked for transplantation, they were found to be without any viable cells. The customer has no idea what happens to the stored unit if the facilities closes or in natural calamities. There are several gray areas that need to be addressed.

**8. Where can one complaint against the UCB banks?**

Complaints regarding unethical practices can be made to zonal offices of CDSCO with copy to central CDSCO and ICMR. One can also move to consumer court.

**9. Which company/banks should the baby's UCB be stored?**

The UCB should be stored only in the UCB banks that are licensed by CDSCO. Regarding which licensed UCB banks to be chosen, it is solely one's own judgment to decide on which company is the best. However, it may be noted that as per National Guidelines for Stem Cell Research - 2017:

*Umbilical Cord Blood (UCB) is a rich source of CD34+ hematopoietic and mesenchymal (stromal) stem cells. Use of UCB derived HSCs for treatment of various haematological and immunological disorders is currently well established, particularly where an HLA-matched sibling is not available. However, there is a paucity of public funded UCB banks in India. On the other hand several private banks have come-up, that engage themselves in promotional advertisements offering storage of cord blood with the promise of future therapeutic use. Such advertisements are often misleading for the public and lack comprehensive and accurate information. So far there is no scientific basis for preservation of cord blood for future self-use and this practice therefore raises ethical and social concerns. Private storage of the cord blood HSCs is advisable when there is an elder child in the family with a condition treatable with these cells and the mother is expecting the next baby. In other situations, the parents should be educated about the limitations of banking at this point of time.*