

## **Institute of Medicine (IOM) Study on Cord Blood Stem Cell Banking Executive Summary of Informed Choice Recommendations**

### **Study Background: U.S. Congress Tasks IOM with Providing Perspective on Key Issues**

In light of increased scientific and political focus on the therapeutic benefits of cord blood stem cells, Congress authorized \$10 million in 2004 for the establishment of a National Cord Blood Stem Cell Bank to oversee the collection, distribution and use of cord blood donations in the U.S. As part of the appropriation, Congress asked the Institute of Medicine (IOM) to initiate a study to review existing cord blood programs, and provide science-based analysis and independent guidance on the ideal structure, function and utility of a national banking program.

To conduct the study, the IOM assembled a committee of independent experts in several fields of medicine and technology including transplantation; obstetrics and gynecology; stem cell biology; cord blood quality and standards; public health; and health technology assessment as well as the fields of economics; outcomes analysis; biostatistics; patient advocacy; and ethics.

After a year of research and analysis, the IOM committee issued its report, “Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program” to the U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) and the public.

The committee asserted that a national cord blood banking program should have as a primary goal to maximize access to high-quality cord blood stem cells for patient care and research in the most efficient, cost-effective and ethical manner possible. The committee also agreed on several key goals for the program including:

- **Simplicity:** A national program needs to avoid duplication of effort.
- **Quality:** The program should promote the best possible chance of patient recovery.
- **Patient and Physician Support:** Education is an integral and necessary part of the program.

### **Key IOM Recommendations: Education and Ethics**

In analyzing the issues involved with creating a national banking program, the IOM cord blood committee recognized that there are several ethical considerations associated with the collection, storage and use of donated tissue for transplantation. Specifically, the committee emphasized that before a donor consents to donate cord blood, she must fully comprehend: who has access to the cord blood once donated; where it will be stored; how it will be stored; how her privacy will be protected and whether the donor stands to gain or be harmed by the donation.

Two key recommendations in the study highlight the need for physicians and other pre-natal care providers to provide all expectant parents with an informed choice about the storage or disposal of their newborn's cord blood stem cells and to provide fair and balanced education on all cord blood banking options prior to labor and delivery:

- **Recommendation 5.2: *Informed Consent Should be Obtained Prior to Labor and Delivery.***  
Informed consent for the collection, storage and use of cord blood should be obtained before labor and delivery, and after the adequate disclosure of information.
- **Recommendation 5.3: *Donors Must Be Provided with Clear Information about their Options.***  
The information provided to a donor must include a balanced perspective on the different options for banking (family banking or public donation). The information disclosed for donation should not include language that gives the impression that the unit will be available to the family after donation.

## **IOM Study Shapes National Public Health Policy**

Following the guidance of the IOM Study, Congress passed and President George W. Bush signed into law the "Stem Cell Therapeutic and Research Act of 2005," which created a new Federal program to collect and store cord blood, and expand the current bone marrow registry program to also include cord blood. A Senate Committee Report that accompanied the Act (H.R. 2520, S. 1317) and recommended passage, included perspective on the IOM Study recommendations on cord blood education:

*"The committee strongly supports the IOM report recommendation that women be provided with a balanced perspective and clear information in order to participate, actively and knowledgably, in the choice of whether or how to donate cord blood. Informed consent is likely to include, at least, consideration of the following options: public donation or private storage; and disposal."*

The IOM Study has helped to guide health policy at the state level as well. To date, 17 states have passed some form of cord blood education legislation, which benefits about two-thirds of the U.S. population. Several other states are in various stages of developing similar legislation to help physicians and expectant parents understand the options for preserving cord blood stem cells.

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