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## **CORD BLOOD EDITORIAL BACKGROUND AND FACT SHEET**

Since the late 1980s, umbilical cord blood and related birthing tissues have evolved from medical waste to a rich source of stem cells that can be transplanted to restore normal development and function in blood diseases such as leukemia and lymphoma, inherited genetic disorders, bone marrow failure and immune deficiency diseases.

Preliminary data in clinical studies suggest that cells contained in umbilical cord blood may be able to repair organ injuries, treat cardiac and vascular disorders, ameliorate immune conditions such as diabetes, and treat neurological disorders including autism, cerebral palsy, spinal cord injury and stroke.

### **Stem Cell Donor Alternatives**

The search for a suitable donor for patients who need a hematopoietic stem cell transplant begins within the family. Brothers and sisters with the same parents have a 25% chance of being a perfect match. However, about 70% of patients do not have a match within the family. For them, physicians can search registries around the world for a suitable adult bone marrow donor or banked stem cells derived from donated umbilical cord blood.

Among unrelated hematopoietic stem cell transplants today, cord blood is the source for about 40% in pediatric patients and 10% of adult patients.

### **Advantages/Disadvantages of Cord Blood**

Cord blood as a source of hematopoietic stem cells for transplant has several advantages over adult bone marrow. Cord blood stem cells typically have not been exposed to viruses, chemicals and environment pollutants that can alter cell function. Because of a lower number of immune cells, cord blood stem cells also do not have to be matched as closely to the patient as do cells from adult donors. In addition, cord blood is easily banked so it is more quickly available than obtaining stem cells from an adult donor who must be located, consented, tested and harvested. As such, cord blood can be the preferred donor source for patients who have a life-threatening genetic disorder, need a transplant quickly, or have an uncommon tissue type because of their racial or ethnic heritage.

On the other hand, as the number of hematopoietic stem cells in a unit of cord blood is lower than with adult sources, patients undergoing cord blood transplant may take longer to engraft, which can increase the risk of transplant-related mortality and morbidity. These disadvantages are being addressed in current laboratory and clinical research on stem cell expansion and homing.

## Number of Patients Treated

More than 60,000 patients have benefited from cord blood transplants since the first transplant in 1988. Currently, cord blood comprises 12% of the stem cell transplant matches facilitated by global registries.

## Spectrum of Diseases Treated

At least 80 blood cancers, genetic diseases and immune system and metabolic disorders can be treated or cured with components found in cord blood. (A list of these diseases is available online at <http://www.cb-association.org/indications-for-utilization-of-stored-umbilical-cord-blood>.)

## Cord Blood Donation Rates

Cord blood donation rates vary from country to country. In the United States, where upwards to 4 million babies are born each year, cord blood is collected in fewer than 5% of births.

## First Cord Blood Transplant

The first cord blood transplant was performed in 1988 at L'Hospital St. Louis in France, using matched sibling cord blood to treat a 5-year-old child with Fanconi anemia. The donor was his newborn sister. The patient is alive and well today, 30 years later.

## First Unrelated Donor Cord Blood Transplant

The first cord blood transplant between an unrelated patient and donor was in 1993 – a 4/6 match in a 4-year-old child with T-cell leukemia, performed at Duke University Medical Center.

## First Cord Blood Transplant in an Adult

The first cord blood transplant in an adult was in 1995 for a patient with leukemia at Duke University Medical Center. Previously, umbilical cord blood transplants were limited to children because of the relatively small number of stem cells in a unit of cord blood.

## First Multi-Center Clinical Study

The first multi-institution, prospective study of unrelated donor cord blood transplantation was the Cord Blood Transplantation Study (COBLT), conducted from 1999-2004.

## Public Cord Blood Banks

The first public cord blood bank was established in 1991 at the New York Blood Center. Around the world today there are more than 800,000 units of cord blood stored in public banks. A [directory of bank registries](#) is maintained by the World Marrow Donor Association (WMDA).

## Family Cord Blood Banks

The first family cord blood banks were Cord Blood Registry established in 1992 and Viacord created in 1993. Around the world today close to 6 million

units of cord blood are stored in nearly 200 private or family cord blood banks in 60 countries.

## Cord Blood Registries

International registries for cord blood unit search were established by the International NetCord Foundation in 1996 and the National Marrow Donor Program/BeTheMatch in 2001. The World Marrow Donor Association (WMDA) in 2017 created a [Search & Match Service](#), a global database for all cord blood units available for transplantation.

## Cord Blood Banking Standards and Accreditation

Standards and voluntary accreditation programs for cord blood banks are maintained by AABB and the Foundation for the Accreditation of Cellular Therapy (FACT). Health professionals and expectant parents can look for these bank accreditations.

## Regulation of Cord Blood Banks

Cord blood banking regulations vary widely among countries that have regulations. In Australia, banks have been regulated by the Australian Therapeutic Goods Administration (TGA) since 2007. In the European Union, regulations have been under the European Directives for Tissues and Cells since 2004. In the United States, the Food & Drug Administration (FDA) issued a final guidance for licensure of unrelated donor cord blood banks in 2011.

## Current Clinical Trials

As of December 2021, there were [93 active clinical trials](#) studying the use of cord blood to treat numerous diseases. In the case of cerebral palsy, ischemic stroke and autism, Duke University trials are currently in Phases II and III. Innovations in cord blood such as Omidubicel, an ex-vivo expanded hematopoietic progenitor cell and nonexpanded myeloid and lymphoid cell product derived from a single umbilical cord blood unit, has passed the clinical trial phase.

## Government Support of Cord Blood Banking

In the United States, the Stem Cell Act of 2005 created the C. W. Bill Young Cell Transplantation Program that is administered through the Health Resources and Services Administration. It partially funds the National Cord Blood Inventory (NCBI), the National Marrow Donor Program/BeTheMatch cord blood registry, the NMDP's cord blood coordinating center for adult and cord blood donors, NMDP's patient advocacy group and the Stem Cell Transplant Outcomes Database (SCTOD).

## Cord Blood Association

The Cord Blood Association, an international, non-profit association for public and family banking, was established in 2014. Its priorities are quality products and services, advocacy, market expansion, research and development, and public and health professional education.