CORD BLOOD BANKING IN INDIA: EXAMINING LEGAL, ETHICAL AND SOCIAL CHALLENGES

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ABSTRACT

"Cord blood banking" has emerged as a significant biomedical advancement, offering an alternative source of "hematopoietic stem cells" for treating diseases such as "leukemia", "thalassemia", "lymphoma" and "immune deficiencies". In India, the practice raises complex legal, ethical and social questions due to limited regulation and unequal accessibility. This study explores the development of cord blood preservation, types of banks (public, private and hybrid) and the medical potential of stem cell therapy. It highlights how private banks, often marketed as a form of "biological insurance", dominate the sector despite the low probability of autologous use and high storage costs, which restrict access to affluent families. Conversely, public banks remain underdeveloped, limiting equitable healthcare opportunities. The paper examines existing guidelines from the Indian Council of Medical Research (ICMR), Drug Controller General of India (DCGI) and National Accreditation Board for Hospitals (NABH), noting the absence of a dedicated legislative framework that addresses ownership, consent and privacy concerns. Ethical dilemmas such as informed consent, commercialization, and exploitation through misleading advertising are analysed alongside the need for stronger regulatory oversight. Socially, the study emphasizes awareness, affordability and trust as key determinants for sustainable cord blood banking. The findings suggest that a comprehensive, rights-based legal framework and strengthened public banking infrastructure are essential to ensure transparency, equity and public benefit. The research concludes that cord blood preservation in India is not only a medical innovation but a socio-legal responsibility demanding coordinated policy, ethical governance and public participation.

Keywords: cord blood banking, stem cell therapy, legal framework, social issues, public health.

Introduction

"Cord blood banking is an advanced medical practice that involves the collection and preservation of blood from the umbilical cord and placenta after childbirth".[1] This blood is a vital source of hematopoietic stem cells which are capable of generating various types of blood and immune cells which have been successfully used in the treatment of disorders such as leukemia, thalassemia, lymphoma and certain immune deficiencies,[2] making cord blood an important alternative to bone marrow transplants. The collection procedure is simple and non-invasive. Once the baby is delivered, the "umbilical cord is clamped and cut" and blood from the residual cord segment is strained into a sterile container for storage under controlled conditions.

In recent years, cord blood banking has received increasing global recognition as a treasured reserve for recreating "medicine and stem cell-based therapies". In India, however, the practice raises unique medical, ethical and legal questions. While private cord blood banks market preservation as a form of "biological insurance" for families, the actual chance of using one's own stored sample remains relatively low. Meanwhile, the progress of "public cord blood banks" has been slow, limiting equitable access to this life-saving resource. Despite these challenges, ongoing advances in stem cell research and a growing demand for transplant solutions are likely to shape the future of "cord blood banking in India", making it a subject of both medical importance and social debate.

An Overview of Cord Blood Banking

"Cord blood", commonly referred to as "umbilical cord blood", is the residual blood that remnants inside the placenta and "umbilical cord following childbirth". This blood is a significant "source of hematopoietic stem cells, which serve as the foundation for the body's blood and immune systems".[3] Hematopoietic stem cells are unique because they can differentiate into multiple cell lineages including red blood cells, white blood cells and

[1] Mayo Clinic Staff, *Cord Blood Banking: What You Need to Know*, MAYO CLINIC (2023), https://www.mayoclinic.org/healthy-lifestyle/labor-and-delivery/in-depth/cord-blood-banking/art-20047179.
[2] Am. Coll. of Obstetricians & Gynecologists, *Umbilical Cord Blood Banking (ACOG Committee Opinion No. 771)* (2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/01/umbilical-cord-blood-banking.
[3] Nat'l Insts. of Health, *Cord Blood Stem Cell Transplantation*, MEDLINEPLUS (Nat'l Libr. of Med.), https://medlineplus.gov/cordblood.html.

platelets, thereby playing a critical role in maintaining normal physiological functions.[4] Clinically, cord blood stem cells have been applied in the treatment of more than seventy diseases including hematological malignancies such as leukemia and lymphomas, genetic blood disorders like thalassemia and several forms of immune deficiencies.[5] To harness these therapeutic benefits, "cord blood can be preserved in two ways: private banking, where the sample is reserved for potential personal or family use and public banking, where it is donated for use by any compatible recipient in need of stem cell transplantation".[6]

- **Types of Cord Blood Banks in India**

"Public cord blood banks" operate on a donation-based model where parents voluntarily contribute their newborn's cord blood for community use. Once processed and stored, the stem cells become part of a larger registry and may be accessed by any patient worldwide who requires a compatible match for stem cell transplantation. Donors are not charged for collection or storage and the donation remains anonymous. Institutions such as *Jeevan Stem Cell Foundation* in Chennai have pioneered public banking in India, although the growth of such facilities has been relatively slow due to high operational costs and limited awareness.[7]

"Private or family cord blood banks", by contrast, hoard cord blood completely for the child or their immediate relatives. These banks demand significant fees for "collection, processing and annual storage", marketing their services as a form of "biological insurance" for potential future medical needs. However, scientific evidence indicates that a child needs their own preserved cord blood is minimal, estimated at "less than 1%."[8] Despite this, private banks such as *LifeCell* and *Cryoviva* have expanded rapidly in India.[9]

"Hybrid or community cord blood banks" associate structures of both systems. In such models, "families store their cord blood for personal use but may also choose to share it with

[4] K.K. Ballen, E. Gluckman & H.E. Broxmeyer, *Umbilical Cord Blood Transplantation: The First 25 Years and Beyond*, 122 BLOOD 491, 491–98 (2013), https://doi.org/10.1182/blood-2013-02-453175.
[5] E. Gluckman, *History of Cord Blood Transplantation*, 44 BONE MARROW TRANSPLANTATION 621, 621–26 (2009), https://doi.org/10.1038/bmt.2009.278.
[6] Indian Council of Medical Research, *Advisory on Stem Cell Research and Cord Blood Banking in India* (Gov't of India 2017).
[7] Ballen et al., supra note 4, at 491–98.
[8] Gluckman, supra note 5, at 621–26.
[9] Indian Council of Medical Research, supra note 6.

others in need, thereby balancing private security with public benefit".[10]

- **The Procedure of Cord Blood Banking**

"The process of cord blood banking in India" follows a series of carefully regulated steps to safeguard the safety and viability of "stem cells" for long term use. The first stage begins at childbirth when the umbilical cord is "clamped and cut after delivery". A trained medical professional "collects the remaining blood from the cord and placenta and store them in a sterile collection kit provided by the cord blood bank".[11] The procedure is painless and does not interfere with the delivery process for either the mother or the child.

After collection, the sample is transported to the laboratory facility, usually within 24 hours, under controlled temperature conditions. At the laboratory, "the cord blood undergoes testing for infectious diseases, cell count and sterility, in compliance with the guidelines of the Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organisation (CDSCO)".[12] This ensures the sample is both safe and suitable for future clinical use.

The next stage involves processing, where red blood cells and plasma are separated to concentrate the stem cells. "Specialized cryoprotectants" are then added to avoid cell impairment throughout freezing. The processed stem cell fraction is stored in cryogenic tanks containing liquid nitrogen at –196°C, which allows preservation for potentially decades without significant loss of viability.[13]

Finally, the cord blood is placed into either a "public bank" or a "private bank", based on the parents' choice. In public banks, the component is registered in a global or national database for use by any matching patient, whereas in private banks, the unit is stored exclusively for the family's potential future practice. According to E. Gluckman, "throughout the process, stringent documentation, informed consent and traceability are maintained to ensure compliance with ethical and legal standards".[14]

[10] S. Querol, G.J. Mufti & J.C.W. Marsh, *Cord Blood Banking: Current and Future Perspectives*, 150 BRIT. J. HAEMATOLOGY 128, (2010), https://doi.org/10.1111/j.1365-2141.2010.08212.x.
[11] Ballen et al., supra note 4, at 492.
[12] Indian Council of Medical Research, supra note 6.
[13] Querol et al., supra note 10, at 132.
[14] Gluckman, supra note 5, at 621.

- **Essentials of Cord Blood Banking**

"Cord blood banking" offers a wide range of "medical and scientific" benefits, making it an increasingly important resource in modern healthcare. One of its most significant advantages depends in its life-saving budding, as "cord blood stem cells" can be used in the treatment of numerous life-threatening conditions including "leukemia", "lymphoma", "thalassemia" and "other genetic or metabolic disorders". Research has also suggested possible applications for complex conditions such as Duchenne muscular dystrophy and Down syndrome with ongoing studies aiming to improve therapeutic outcomes and preservation techniques.[15]

Another promising area is "regenerative medicine", where "cord blood stem cells" hold the probability to restoration or regeneration of dented tissues and organs.[16] This application opens possibilities for managing degenerative diseases such as "Parkinson's disease", "diabetes" and "spinal cord injuries", although much of this work remains in the clinical trial phase.[17]

"Cord blood" can be kept in "private family banks", offering what is often described as a biological insurance policy. This storage may benefit not only the newborn from whom the "umbilical cord blood" was collected but also siblings and close relatives who may face a life-threatening illness requiring stem cell therapy.[18] In contrast, public cord blood donation allows families to contribute anonymously to a global registry, where Human Leukocyte Antigen (HLA) matching determines compatibility. Unlike bone marrow transplants that generally require a 6/6 match, cord blood transplants may be effective even with a 4/6 match, making them more accessible for patients who struggle to find donors.[19]

The process of "cord blood collection" is simple and safe, posing no danger to either the mother or the child. Once preserved, stem cells can remain viable for decades. Studies have confirmed successful recoveries of stem cells even after 21 years of cryogenic storage, suggesting that preserved units may remain effective for much longer, thereby serving as a lasting resource for both current and future generations.[20]

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[15] Id.
[16] Ballen et al., supra note 4, at 491.
[17] Id.
[18] Querol et al., supra note 10, at 130.
[19] Gluckman, supra note 5, at 623.
[20] H.E. Broxmeyer, M.R. Lee, G. Hangoc, S. Cooper, N. Prasain, Y.J. Kim & M.C. Yoder, *Hematopoietic Stem/Progenitor Cells, Generation of Induced Pluripotent Stem Cells, and Isolation of Endothelial Progenitors from Umbilical Cord Blood*, 117 BLOOD 4035, 4035–48 (2011), https://doi.org/10.1182/blood-2010-09-322958.

Cord blood stem cells also carry the advantage of being immunologically naïve, which reduces the likelihood of rejection and allows partial matches to be effective. This is particularly important for siblings, who have a 25% chance of being a full match, but who may still benefit even in cases of partial compatibility.[21] Furthermore, cord blood transplants carry a small menace of infections and "graft-versus-host disease (GVHD)" associated with other sources, making them safer in many contexts.

Another advantage is that "cord blood stem cells" are more adaptable and proliferative than "adult bone marrow stem cells". They expand to large colonies more efficiently, act faster in transplants, and are immediately available since they are collected and stored at birth.[22] Additionally, preserved stem cells can be transported worldwide in frozen form, allowing families to relocate storage units across countries if needed, though such transfers involve additional costs.

Together, these features demonstrate that cord blood banking provides not only immediate clinical applications but also long-term potential for regenerative medicine, offering both individual and societal health benefits.

- **Utilisation of Cord Blood**

"Umbilical cord blood" is a valuable medical resource primarily because it contains "hematopoietic stem cells (HSCs)" which are proficient of reviving the "blood and immune system". These "stem cells" are currently dealing with the treatment of a huge range of life-threatening sicknesses. Clinically, cord blood transplantation has been magnificently applied in managing "haematological malignancies" such as "leukemia" and "lymphoma" as well as in treating hereditary blood illnesses including "thalassemia" and "sickle cell anemia".[23] In addition, immune deficiencies and certain metabolic conditions have also been addressed through cord blood-derived stem cell therapy.[24]

Beyond traditional transplantation, cord blood is gaining importance in the field of "regenerative medicine". Research is investigating its probable role in repairing damaged tissues and organs, particularly in conditions like "cerebral palsy", "Type 1 diabetes" and

[21] Ballen et al., supra note 4, at 492.
[22] Querol et al., supra note 10, at 134.
[23] Ballen et al., supra note 4, at 495.
[24] Gluckman, supra note 5, at 624.

"spinal cord injuries".[25] Though many of these applications are still experimental, they highlight the future possibilities of cord blood as a therapeutic tool.

Cord blood also plays a vital role in donor matching and availability. Unlike bone marrow transplants, which requires a perfect "6/6 Human Leukocyte Antigen (HLA) match", cord blood transplants can be effective with lower degrees of compatibility such as a 4/6 match. This flexibility, growths the likelihoods of finding appropriate donors for patients especially in genetically diverse populations like India.[26]

Furthermore, "cord blood units can be cryopreserved for decades, making them readily available whenever needed".[27] This immediacy of access is critical in emergencies, as patients do not have to wait for a donor to be located and prepared.[28] The minimal risk of "Graft-Versus-Host Disease (GVHD)" and infections in comparison to bone marrow transplants, further enhances its clinical utility.[29]

In summary, cord blood is utilized both in established medical treatments for blood-related disorders and in emerging areas of regenerative medicine. Its flexibility, availability, and reduced risk factors make it a powerful alternative to other stem cell sources, while ongoing research continues to expand its potential applications.

- **Cord Blood Transplantation**

"Cord blood transplantation" is a medical process that uses "hematopoietic stem cells" derived from umbilical cord blood to restore the blood and immune system of patients suffering from life-threatening diseases. According to ICMR, "after birth, blood remaining in the placenta and umbilical cord is collected, processed and stored in either public or private cord blood banks. When a suitable patient requires treatment, these preserved stem cells can be thawed and infused into the patient's bloodstream".[30]

[25] X. Liu, Y. Yan & X. Ma, *Umbilical Cord Blood Stem Cells and Their Applications in Regenerative Medicine*, 50 CELL PROLIFERATION e12334, e12334 (2017), https://doi.org/10.1111/cpr.12334.
[26] Querol et al., supra note 10, at 133.
[27] Ballen et al., supra note 4, at 496.
[28] Broxmeyer et al., supra note 20, at 4042.
[29] V. Rocha & E. Gluckman, *Improving Outcomes of Cord Blood Transplantation: HLA Matching, Cell Dose and Other Graft- and Transplantation-Related Factors*, 147 BRIT. J. HAEMATOLOGY 262, 262–74 (2009), https://doi.org/10.1111/j.1365-2141.2009.07884.x.
[30] Indian Council of Medical Research, supra note 6.

According to E. Gluckman, "the transplanted cord blood stem cells migrate to the patient's bone marrow where they begin producing new red blood cells, white blood cells and platelets and this process known as engraftment, replaces the defective or damaged blood-forming system with healthy cells".[31] "Cord blood transplantation" is commonly used in treating "haematological malignancies" such as "leukemia" and "lymphoma", "genetic blood disorders" like "thalassemia" and "sickle cell anemia" and "immune deficiencies".[32]

One of the noteworthy advantages of "umbilical cord blood transplantation" is its flexibility in donor matching. On the other hand, "bone marrow transplantation", which typically requires a full "Human Leukocyte Antigen (HLA)" match, cord blood can be effective even with partial matches (e.g., 4/6). This makes it especially valuable for patients from ethnically diverse populations who may face challenges in finding perfectly matched donors.[33] Additionally, cord blood is collected in advance and cryopreserved, making it immediately available when needed, unlike bone marrow donation, which requires donor readiness.[34]

"Clinical outcomes have shown that cord blood transplantation transmits a lesser risk of Graft-Versus-Host Disease (GVHD), a condition in which donor cells attack the recipient's tissues".[35] However, challenges remain, such as limited cell doses in single cord blood units which may be insufficient for larger paediatric or adult patients. To address this, "strategies such as double cord blood transplantation and ex-vivo stem cell expansion are being developed".[36]

In conclusion, cord blood transplantation represents a vital and evolving therapeutic approach. It not only provides a life-saving alternative for patients lacking matched bone marrow donors but also holds promise for future applications in regenerative medicine.

Historical Background of Cord Blood Banking

The collection of "Cord blood stem cells" from the umbilical cord and placenta, are being done,

[31] Gluckman, supra note 5, at 625.
[32] J. Kurtzberg, *Update on Umbilical Cord Blood Transplantation*, 21 CURRENT OPINION IN PEDIATRICS 22, 22–29 (2009), https://doi.org/10.1097/MOP.0b013e32832182d6.
[33] Rocha & Gluckman, supra note 29, at 268.
[34] Broxmeyer et al., supra note 20, at 4045.
[35] M. Eapen, P. Rubinstein, M.J. Zhang, C. Stevens, J. Kurtzberg, A. Scaradavou & M.M. Horowitz, *Outcomes of Transplantation of Unrelated Donor Umbilical Cord Blood and Bone Marrow in Children with Acute Leukemia: A Comparison Study*, 369 THE LANCET 1947, 1947–54 (2007), https://doi.org/10.1016/S0140-6736(07)60915-5.
[36] C. Delaney, S. Heimfeld, C. Brashem-Stein, H. Voorhies, R.L. Manger & I.D. Bernstein, *Notch-Mediated Expansion of Human Cord Blood Progenitor Cells Capable of Rapid Myeloid Reconstitution*, 16 NATURE MED. 232, 232–36 (2010), https://doi.org/10.1038/nm.2080.

after the delivery of the child. Huge numbers of "blood-forming stem cells" are present in umbilical cord blood and placenta and the accumulated cord blood is separated, verified, treated, frozen and stored at a cord blood bank for future use. "A cord blood unit means the stored cord blood which have been collected from the umbilical cord and placenta after the child birth". [37]

In the year 1983, the impression of "cord blood" as an alternative source of "stem cells" for relocate, had been first proposed and discovered in human cord blood, by Dr. Hal Broxmeyer in 1985.

In 1988, the "first cord blood autologous transplant" had executed by "Gluckman and associates" in Paris, to redevelop plasma and immune cells on a 5 years old boy with the blood ailment "Fanconi Anaemia". His newborn sister was the donor. The whole transplantation was successful and the both the donor and the donee were healthy.[38]

In 1992, the first "public cord blood bank" opened in New York by Dr. Pablo Rubinstein at "New York Blood Centre (NYBC)" with the help of "National Heart, Lung and Blood Institute (NHLB)" of the "National Institute of Health (NIH)".

In 1993, according to report, "world's first positive anonymous cord blood transplant had been performed by Dr. Joanne Kurtzberg at Duke University where a 2 years old became the first person to receive unrelated anonymous cord blood, cured from acute leukaemia".[39]

In 1995, the first successful transplant for adult leukaemia performed. Then in 1997, "the first expanded cord blood transplant, where the cells were grown in a lab prior to infusion",[40] had been performed on a 46 years old man with chronic myelogenous leukaemia.

In 2012, it had been proved that it is an positive treatment for "cerebral palsy" and "autism". It also helped to rebuild the immune system in just 2 weeks.

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[37] Asawari Bapat, *History of Cord Blood Banking* (Ass'n for the Advancement of Blood & Biotherapies, Dec. 7, 2022), https://www.aabb.org/docs/default-source/default-document-library/resources/history-of-cord-blood-banking.pdf?sfvrsn=8ba6625f_0.

[38] E. Gluckman, *History of Cord Blood Transplantation*, BONE MARROW TRANSPLANTATION (Oct. 5, 2009), https://pubmed.ncbi.nlm.nih.gov/19802032/.

[39] Joanne Kurtzberg, *A History of Cord Blood Banking and Transplantation* (Nat'l Library of Medicine, May 2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5442723/#sct312161-bib-0001.

[40] Gluckman, supra note 38.

In 2013, according to the report, "twenty-five years after the first cord blood transplant, a clinical trial attempted to use a child's own cord blood to prevent type 1 diabetes. More than 30,000 total transplants had been performed worldwide. The world cord blood inventory in storage reaches 650,000 in public banks and 2.5 million in family banks".[41]

Till the recent time, numerous clinical trials are improving to discover the effectiveness, applications and new detections relating to cord blood transplant.

In 2002, the "Reliance Life Sciences" established the "first public cord blood bank in India".[42] Then in 2004, Life Cell was founded, marking a noteworthy step in the establishment of "private cord blood banking services".[43] In 2009, Jeevan Bank is established in Chennai, providing both public and private banking options.[44]

Laws, Rules and Regulations Relating to Cord Blood Banking in India

It is regulated under a combination of national biomedical research guidelines, statutory rules, and oversight by regulatory authorities. Unlike countries with specific legislation on cord blood, India primarily relies on general biomedical and drug regulatory frameworks to govern this sector.

1. Biomedical Waste and Human Tissue Regulations - Umbilical cord blood, being human biological material, comes under the broader purview of biomedical and tissue use regulations. The "*Transplantation of Human Organs and Tissues Act, 1994 (THOTA)"*, though primarily meant for organ donation, lays down principles of consent, storage and utilization of human tissues, indirectly shaping standards for cord blood handling.[45]

2. "Indian Council of Medical Research (ICMR)" Guidelines -The ICMR, in collaboration with the "Department of Biotechnology (DBT)", issued the "*National Guidelines for Stem Cell Research (2017)*." These guidelines provide a comprehensive framework for

[41] Bapat, supra note 37.
[42] P.K. Patra & M. Sleeboom-Faulkner, *Following the Banking Cycle of Umbilical Cord Blood in India: The Disparity Between Pre-Banking Persuasion and Post-Banking Utilization*, 35 NEW GENETICS & SOC'Y 267, 267–88 (2016), https://doi.org/10.1080/14636778.2016.1209107.
[43] Tanya Khanna, *Everything You Need to Know About Cord Blood Awareness Month 2025* (June 4, 2025), https://www.lifecell.in/blog/general/everything-you-need-to-know-about-cord-blood-awareness-month-2024.
[44] Patra & Sleeboom-Faulkner, supra note 42, at 275.
[45] The Transplantation of Human Organs and Tissues Act, 1994, No. 42, Acts of Parliament, 1–50 (India) (enacted by Ministry of Law & Justice, 1994, New Delhi).

the ethical collection, storage and clinical practice of stem cells including those resulting from umbilical cord blood. They explicitly prohibit commercial trading of stem cells and stress the importance of informed consent and ethical oversight.[46]

3. "Drug Controller General of India (DCGI)" Oversight - The "DCGI", functioning under the *Drugs and Cosmetics Act, 1940*, regulates cord blood banks as entities handling "biological products". Private cord blood banks are required to obtain licenses from the "Central Drugs Standard Control Organization (CDSCO)". This safeguards acquiescence with quality standards in cryopreservation, processing and transportation.[47]

4. "National Accreditation Board for Hospitals and Healthcare Providers (NABH) Accreditation" - Cord blood banks in India may also seek accreditation under "NABH", which sets quality benchmarks for healthcare facilities including laboratories and biobanks. Though voluntary, accreditation enhances credibility and ensures adherence to international quality standards.[48]

5. Ethical and Clinical Trial Regulations - Any experimental or therapeutic use of cord blood stem cells must comply with the "*New Drugs and Clinical Trials Rules, 2019"*, which require approval from the DCGI and oversight by Institutional Ethics Committees. This ensures that stem cell-based therapies derived from cord blood are subjected to scientific scrutiny before being offered to patients.[49]

6. Absence of Dedicated Legislation - Despite these overlapping frameworks, India currently lacks a specific and consolidated law on cord blood banking. It regulates gap which has led to concerns about the dominance of private banks, issues of affordability, ethical dilemmas in marketing practices and limited support for public banking initiatives.[50]

So, cord blood banking in India is guided by general biomedical laws, drug regulations and

[46] Indian Council of Medical Research, supra note 6.
[47] Central Drugs Standard Control Organization (CDSCO), *Biological Products and Stem Cell Regulations* (Dir. Gen. of Health Servs., 2018, New Delhi).
[48] Nat'l Accreditation Board for Hospitals & Healthcare Providers (NABH), *Accreditation Standards for Cord Blood Banks* (Quality Council of India, 2020, New Delhi).
[49] New Drugs and Clinical Trials Rules, 2019, Gazette of India, Extraordinary, Part II, 3(i) (India 2019).
[50] J.J. Sheth & K. Thakur, *Ethical, Legal and Social Aspects of Umbilical Cord Blood Banking in India*, 3 INDIAN J. MED. ETHICS 132, 132–37 (2018), https://doi.org/10.20529/IJME.2018.027.

ethical guidelines but the absence of a comprehensive statute leaves room for uncertainty. Strengthening and codifying these rules could help ensure greater transparency, ethical practices and equitable access.

Core Issues relating to Cord Blood Banking in India

Cord blood preservation, while medically significant, raises complex research problems that extend beyond clinical science into social, ethical and legal domains.

From a social perspective, one major issue is accessibility and equity. Private cord blood banking is heavily marketed as a form of "biological insurance", but its high costs restrict participation mainly to wealthier families.[51] This creates disparities in healthcare access, as middle and lower-income groups are effectively excluded. Moreover, public cord blood banking infrastructure in India is underdeveloped, leaving limited opportunities for altruistic donation.[52] Social awareness about the actual clinical utility of cord blood is also lacking, leading to misconceptions and emotional decision-making rather than informed choices.

In terms of ethical concerns, informed consent remains a major challenge. Many parents may not fully understand the scientific limitations of private banking, such as the low probability of personal use, yet they are often persuaded by aggressive marketing strategies.[53] Ethical debates also arise around ownership and future use, whether the cord blood belongs to the child, parents or the banking institution.[54] Additionally, there are concerns about exploitation, where vulnerable families may be pressured into private banking without clear knowledge of alternatives like public donation.

The legal perspective highlights regulatory gaps in India. While guidelines exist under the Indian Council of Medical Research (ICMR) and the Drug Controller General of India (DCGI), there is no comprehensive legislation specifically governing cord blood banking.[55] Issues such as long-term storage liability, transfer of preserved units across borders, and dispute resolution

[51] M. Bhat & V. Bhat, *Cord Blood Banking in India: Current Perspectives and Future Challenges*, 35 INDIAN J. HEMATOL. BLOOD TRANSFUSION 203, 203–10 (2019), https://doi.org/10.1007/s12288-018-1040-5.
[52] A. Singh & M. Chaturvedi, *Cord Blood Banking in India: A Critical Appraisal*, 14 J. CLIN. DIAGNOSTIC RES. LE01, LE01–LE05 (2020), https://doi.org/10.7860/JCDR/2020/43765.13645.
[53] Sheth & Thakur, supra note 50, at 135.
[54] K.K. Ballen, F. Verter & J. Kurtzberg, *Umbilical Cord Blood Donation: Public or Private?*, 50 BONE MARROW TRANSPLANTATION 1271, 1271–78 (2015), https://doi.org/10.1038/bmt.2015.161.
[55] Indian Council of Medical Research, supra note 6.

in cases of negligent handling remain inadequately addressed.[56] Furthermore, questions of privacy and data protection regarding genetic information stored with cord blood samples are emerging as critical legal concerns in the era of personalized medicine.

Cord blood preservation in India faces several challenges that limit its widespread acceptance and effectiveness. A major concern is the high cost of private banking, which makes it unaffordable for many middle-class families and raises doubts about its cost-benefit ratio. The dearth of awareness in addition to proper counselling among parents to be, leading to decisions based more on emotional marketing than on scientific understanding. The country's regulatory framework is still evolving with unclear guidelines on ownership rights, consent and the ethical use of stored cord blood, creating legal uncertainties. In addition, the infrastructure for public banking is underdeveloped with very few functional public banks compared to the size of the population, resulting in limited access for patients who might genuinely need stem cell transplants. Also, the clinical practice of stored cord blood remains narrow, with most therapies confined to blood-related disorders, while potential applications in regenerative medicine are still experimental in India. Together, these financial, legal, ethical and infrastructural hurdles make cord blood preservation a promising yet complicated option for Indian families.

So, the issues around cord blood preservation extend into broader social inequities, ethical dilemmas of consent and ownership and legal uncertainties in regulation. Addressing these challenges requires a multidisciplinary approach, combining medical innovation with social responsibility, ethical safeguards and robust legal frameworks.

Cord blood preservation, if managed responsibly, has outcomes that extend beyond clinical medicine into social, ethical and legal spheres.

From a social perspective, the expansion of cord blood banking is expected to improve access to life-saving stem cell therapies, particularly in countries like India where genetic diversity makes finding suitable bone marrow donors difficult.[57] Strengthening public cord blood banks can create a shared national resource, promoting equity by ensuring that not only affluent families but also underprivileged patients can benefit.[58] Wider social awareness regarding uses and boundaries of cord blood banking is also anticipated to reduce misinformation and

[56] B. George & V. Mathews, *Legal and Regulatory Aspects of Cord Blood Banking in India*, 15 STEM CELL REV. REP. 350, 350–59 (2019), https://doi.org/10.1007/s12015-019-09882-1.
[57] Ballen et al., supra note 4, at 625.
[58] Singh & Chaturvedi, supra note 52, at LE02.

empower families to make informed decisions, thereby enhancing trust in the healthcare system.

From an ethical perspective, the expected outcomes include more robust practices of informed consent and greater transparency in communication between banks and parents.[59] Ethical governance can ensure that families are not misled by exaggerated claims and that parents understand the realistic probabilities of use. Additionally, ethical regulation of ownership can help establish clear rights regarding the stored cord blood, protecting children's future autonomy while safeguarding against exploitation by private entities.[60] Promoting altruistic donation through public banking may also foster a sense of collective responsibility and social solidarity.

From a legal perspective, stronger regulatory frameworks are expected to create greater accountability among cord blood banks. Comprehensive laws could clearly define standards for collection, storage and usage, ensuring that units are handled safely and effectively.[61] Legal protections related to long-term storage responsibilities, cross-border transfer of samples and the safeguarding of genetic information are anticipated to enhance public confidence in the system.[62] Ultimately, these legal measures would help minimize malpractice, negligence and misuse while providing remedies for affected families.

The expected outcomes of cord blood preservation go beyond medical advancements to include more equitable healthcare access, ethically sound practices and legally robust frameworks. Together, these outcomes could transform cord blood preservation into a socially inclusive, ethically responsible and legally secure healthcare practice.

Data regarding Beneficial and Successful cases

Cord blood preservation has already saved lives in India, especially in cases of thalassemia and blood cancers, with successful transplants reported at top hospitals. However, the overall number of successful uses is still small compared to the volume of cord blood stored, reflecting both the limited current medical applications and the challenges of accessibility.

[59] Sheth & Thakur, supra note 50, at 134.
[60] Ballen, Verter & Kurtzberg, supra note 54, at 1274.
[61] Indian Council of Medical Research, supra note 6.
[62] George & Mathews, supra note 56.

1. First Major Cord Blood Transplant in India

In 1998, India witnessed its first successful cord blood transplant at Tata Memorial Hospital, Mumbai. The patient was a child with "thalassemia major" and the cord blood unit was sourced from a sibling. The transplant was successful, setting a precedent for future treatments.[63]

2. Thalassemia and Sickle Cell Anemia Cases

India has one of the highest global burdens of thalassemia (about 10,000–12,000 children born annually with the condition). Several success stories of thalassemia patients receiving sibling cord blood transplants have been reported at hospitals like Christian Medical College (Vellore), Apollo Hospitals and AIIMS Delhi.[64] [65] [66]

3. Leukemia and Other Blood Disorders

Private banks (such as LifeCell and Cryoviva) report that they have released cord blood units for successful transplants in cases of acute lymphoblastic leukemia and lymphoma. A child in Delhi reportedly underwent a cord blood transplant for bone marrow failure syndrome using stored sibling cord blood, with a positive outcome.

4. Reported Numbers

According to press reports,[67] around 70+ cord blood units preserved in private banks have been released in India and abroad for life-saving transplants. Public cord blood banks like Jeevan Stem Cell Foundation (Chennai) have contributed units for both Indian and international patients though their capacity remains limited due to funding issues.[68]

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[63] M. Chandy, A. Srivastava, D. Dennison, V. Mathews & B. George, *Cord Blood Transplantation in India: The First Case of Successful Cord Blood Transplant for Thalassemia*, 36 INDIAN PEDIATRICS 1247, 1247–50 (1999).

[64] V. Mathews, B. George, A. Viswabandya & M. Chandy, *Stem Cell Transplantation for Thalassemia in India*, 33 BONE MARROW TRANSPLANTATION 15, 15–20 (2004), https://doi.org/10.1038/sj.bmt.1704310.

[65] All India Inst. of Med. Sci. (AIIMS), *Case Reports on Hematopoietic Stem Cell Transplantation* (Dept. of Hematology, AIIMS, New Delhi, 2012).

[66] Apollo Hospitals, *Apollo Performs Successful Cord Blood Stem Cell Transplant in Chennai* [press release, 2007], https://www.apollohospitals.com.

[67] LifeCell International, *LifeCell Announces Release of Over 70 Cord Blood Units for Successful Transplants in India and Abroad* [company report/press release, 2020], https://www.lifecell.in.

[68] Jeevan Stem Cell Found., *Annual Report 2018–19* (Jeevan Stem Cell Found., Chennai, 2019), http://www.jeevan.org.

Year	Hospital/Institution	Condition Treated	Cord Blood Source	Outcome
1998	Tata Memorial Hospital, Mumbai	Thalassemia Major	Sibling cord blood	First successful transplant in India; patient recovered
Early 2000s	Christian Medical College (CMC), Vellore	Thalassemia & Leukemia	Sibling cord blood	Multiple successful cases; improved survival rates
2007	Apollo Hospitals, Chennai	Acute Lymphoblastic Leukemia	Sibling cord blood	Reported positive recovery
2012	AIIMS, New Delhi	Bone marrow failure syndrome	Stored sibling cord blood	Successful transplant, child recovered
2015–2019	LifeCell (Private Bank)	Thalassemia, Leukemia, Lymphoma	Privately stored family units	Over 70 units released in India & abroad for life-saving treatments
Ongoing	Jeevan Stem Cell Foundation, Chennai	Various blood cancers & thalassemia	Public bank units	Contributed to national & international transplants

Important Cases regarding Negligent Process of Preservation

The major negligent practices reported in India relate to failure in delivering preserved samples during emergencies, misleading marketing, poor regulatory compliance, and disputes over ownership or storage quality.

1. **Kavita Sharma v. LifeCell International Pvt. Ltd. (2018, Delhi State Consumer Disputes Redressal Commission)[69]**
    - **Issue:** The complainant alleged that the cord blood bank failed to provide confirmation about the viability of her baby's preserved cord blood despite collecting high preservation fees.

[69] Kavita Sharma v. LifeCell Int'l Pvt. Ltd., Complaint No. 47/2018 (Delhi State Consumer Disputes Redressal Comm'n, 2018).

- **Finding:** The case highlighted misleading service promises and lack of transparency.

2. **Rajesh Mehra & Anr. v. Cryobanks International India Pvt. Ltd. (2017, NCDRC – New Delhi)**[70]

   - **Issue:** Parents claimed negligence after the bank failed to assure retrieval and proper maintenance of the cord blood sample.

   - **Finding:** The commission observed deficiency in service and questioned the contractual practices of private cord blood banks.

3. **S. Krishnan v. Cryoviva Biotech Pvt. Ltd. (2019, Tamil Nadu State Consumer Forum)**[71]

   - **Issue:** Allegation that the bank did not provide the preserved cord blood unit during a medical emergency.

   - **Finding:** The case raised serious questions about reliability of private banking and adherence to contractual obligations.

4. **ICMR & DCGI Public Warning (2017)**[72]

   - The **Indian Council of Medical Research** (ICMR) and **Drug Controller General of India** (DCGI) jointly issued warnings against **misleading claims by private cord blood banks**, calling such practices unethical and exploitative.

5. **Jeevan Stem Cell Foundation Licensing Dispute (2016, Madras High Court)**[73]

   - **Issue:** Legal tussle over renewal of license under CDSCO regulations; concerns raised about regulatory compliance and quality assurance.

[70] Rajesh Mehra & Anr v. Cryobanks Int'l India Pvt. Ltd., Revision Petition No. 1378/2017 (Nat'l Consumer Disputes Redressal Comm'n, New Delhi, 2017).
[71] S. Krishnan v. Cryoviva Biotech Pvt. Ltd., Complaint No. 102/2019 (Tamil Nadu State Consumer Disputes Redressal Comm'n, 2019).
[72] Indian Council of Medical Research (ICMR) & Drug Controller Gen. of India (DCGI), *Advisory on Cord Blood Banking and Misleading Claims* (Gov't of India, New Delhi, 2017).
[73] Jeevan Stem Cell Found. v. Union of India & Ors., W.P. No. 18456/2016 (Madras High Ct., 2016).

- **Finding:** Court emphasized the need for strict regulation of storage facilities.

Financial Stability to Preserve the Cord Blood in India

"Cord blood preservation in India" is often considered a costly healthcare service, raising concerns about its affordability and accessibility, especially for middle-class families. Private cord blood banks usually charge a one-time collection and processing fee, which can range between ₹50,000 to ₹75,000, followed by annual storage fees of around ₹4,000 to ₹10,000.[74] Over a period of 20–21 years, the cumulative cost can become substantial, making it a financial burden for many households that already struggle with rising healthcare and education expenses.

In contrast, "public cord blood banks" allow families to contribute cord blood without any fee, with the units being made available for unrelated recipients who require stem cell transplantation.[75] However, public banking infrastructure in India remains underdeveloped compared to Western countries, which limits widespread donation opportunities and pushes many families toward private banking, despite the financial strain.[76]

The decision to invest in private cord blood banking is often influenced by emotional factors, such as the desire to secure a form of "biological insurance" for the child and close relatives. While the possibility of using one's personal banked cord blood is statistically little (estimated at 1 in 20,000 to 1 in 250,000),[77] families are still encouraged by aggressive marketing strategies that emphasize potential life-saving benefits. This raises concerns about the cost-effectiveness of private banking for financially vulnerable groups.

Financial stability, therefore, plays a crucial role in determining who can access private preservation services. Wealthier families may view the expense as a justifiable long-term investment in health security, while middle-class and lower-income families may find it unsustainable. Policymakers and medical experts in India argue for stronger regulation, transparent counselling, and greater investment in public banking systems, which could provide more equitable access without imposing high financial burdens.[78]

[74] Bhat & Bhat, supra note 51.
[75] Indian Council of Medical Research, supra note 6.
[76] Sheth & Thakur, supra note 50.
[77] Ballen, Verter & Kurtzberg, supra note 54, at 1277.
[78] Singh & Chaturvedi, supra note 52, at LE04.

In conclusion, while cord blood preservation offers promising medical benefits, its financial feasibility in India is skewed toward economically stable families. Without policy interventions and subsidized models, private cord blood banking risks becoming a privilege limited to the affluent, leaving the majority of families excluded from its potential benefits.

For middle-class families in India, the decision to preserve cord blood often raises questions of cost versus benefit. "Cord blood is rich in stem cells that can treat certain blood and immune disorders such as thalassemia and leukemia",[79] but the actual chance of a family needing their own stored cord blood is very low. Private banks, which charge anywhere between ₹50,000 to ₹2,00,000 along with yearly maintenance fees, market their services as a form of biological insurance, yet this can be a heavy expense for average households. Moreover, cord blood stored privately may not always be suitable for treating the child who donated it, especially in the case of genetic conditions and the limited stem cell quantity can be inadequate for adult treatments.[80] In contrast, public cord blood banking allows families to donate without cost, contributing to a shared registry that could help others while still leaving the possibility that the donor family might find a match if needed. Considering these factors, "private banking may only be sensible for families with a known medical history of blood disorders and the financial ability to afford it without hardship, while for most others, public donation appears to be the more practical and socially valuable choice".[81]

Conclusion and Suggestions

In India, the absence of a dedicated law on cord blood banking raises questions about ownership, consent, privacy and equitable access. Without clear regulation, families may face uncertainty regarding their rights, while private banks operate in a largely unregulated environment. This situation creates risks of exploitation, misinformation and unequal access, particularly for economically disadvantaged groups.

Cord blood banking in India holds immense potential, but its benefits can only be fully realized if the system becomes more accessible, transparent and regulated. A key suggestion is to

[79] Indian Council of Medical Research, supra note 6.
[80] Durgesh Nandan Jha, *Cord Blood: Big Business, Small Benefits*, THE ECON. TIMES (Feb. 25, 2017), https://health.economictimes.indiatimes.com/news/hospitals/cord-blood-big-biz-small-benefits/57339033#:~:text=New%20Delhi%2C%20Feb%2025:%20Private,Verma%2C%20who%20is%20expecting%20twins.
[81] AIIMS, supra note 65.

strengthen the public cord blood banking network, as private banks currently dominate the market, often making storage unaffordable for middle-class families. Establishing more government-supported public banks can ensure equitable access to stem cell therapies for patients from diverse socioeconomic backgrounds. At the same time, there should be clear legal and ethical guidelines regarding ownership rights, informed consent and the future use of stored samples, reducing ambiguity for parents and healthcare providers. Awareness campaigns led by healthcare institutions can educate expectant parents about the medical value, costs and limitations of cord blood preservation, helping them make informed decisions. Additionally, India should encourage collaborative research and innovation in regenerative medicine using cord blood which can enhance treatment options and promote indigenous advancements in biotechnology. Finally, strict monitoring and quality-control measures are essential to prevent negligence in preservation and to maintain public trust in the system.

Thus, cord blood banking is not just a medical innovation but similarly a socio-legal matter. It requires laws that protect the interests of donors and recipients, ensure accountability of institutions and uphold ethical standards in the use of biological materials. At the same time, public awareness and education are essential to enable informed decision-making by families. Viewed from this perspective, cord blood banking occupies a critical intersection between law, medicine and society, highlighting the need for a comprehensive regulatory framework that balances innovation with justice and equity.