



The Ethical Challenges of Umbilical Cord Blood Stem Cell Banking: A Qualitative Study

Madjid SoltaniGerdfaramarzi¹, Seyed Ali Enjoo ², Leila Afshar², Mohsen Fadavi², Mehrzad Kiani ² and Shabnam Bazmi ^{2,*}

¹Royan Stem Cell Technology Company, Tehran, Iran

²Department of Medical Ethics, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

*Corresponding author: Department of Medical Ethics, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Email: sh_bazmi2003@yahoo.com

Received 2023 November 13; Revised 2024 January 22; Accepted 2024 February 21.

Abstract

Background: Umbilical cord blood serves as a potent source of hematopoietic stem cells, utilized in treating specific diseases and preserved in blood banks.

Objectives: This study aims to explore the ethical issues associated with these repositories.

Methods: This qualitative research involved conducting 14 interviews with experts and the families of recipients or donors of umbilical cord blood. Participants were selected purposefully from May to November 2021.

Results: The investigation identified five principal ethical challenges: presentation of information, interpersonal relationships among involved parties, respect for human dignity, adherence to rules and regulations, and the handling of tissue samples. These challenges encompassed various categories and subcategories, including informed consent, communication and advertising of information, financial considerations, conflicts of interest, professional interactions, ownership rights concerning the child and parents, privacy and confidentiality issues, compliance with regulations and guidelines, and the clinical and research uses of the tissue samples.

Conclusions: The study unveiled significant ethical concerns in the domain of umbilical cord blood stem cell banking. Addressing these ethical dilemmas necessitates the involvement of health policymakers and medical ethics experts, along with a comprehensive understanding of these banks' multifaceted nature by the community.

Keywords: Blood Banks, Blood Specimen Collection, Directive Counseling, Fetal Blood, Informed Consent, Ethics

1. Background

With advancements in medical science, diseases once deemed untreatable are now treatable. One such method involves the use of stem cells for treating specific conditions (1). Given that human tissues have carried cultural, educational, and scientific significance, the concept of tissue economies has developed over the past 40 years (2). Cultural values, representing ideals or principles shared among society members, influence the interconnected relationships within these communities (3). Stem cells have become invaluable in transplantation and regenerative medicine. Umbilical cord blood, serving as a source of stem cells for blood regeneration, offers an alternative to bone marrow or peripheral blood progenitor cells (PBPC) (4). Furthermore, umbilical cord blood grafts from both related and unrelated donors

have been utilized to treat children with malignant and non-malignant conditions (5-7).

Stem cells, as a significant product, necessitated the establishment of banks for better preservation and facilitated their trade in both private and public markets (8).

The swift rise and expansion of umbilical cord blood banks have introduced significant challenges, including securing informed consent from donors, verifying ownership, addressing claims of medical benefits, managing commercialization, protecting personal information, and navigating interpersonal relations (9). It's important to acknowledge the absence of definitive ethical, legal, or religious stances regarding donor identity (10).

On July 21, 1998, the European Union issued a statement on the "ethical aspects of human tissue banks"

(11), highlighting principles such as dignity, privacy, confidentiality, promoting solidarity, equity of access, and ensuring donors' informed consent. This statement also clarified that information provided to women or couples must transparently communicate the potential for new treatments, albeit experimental (12). Additionally, it questioned the realism of giving informed consent to a private bank (13).

Despite the significance of the subject and the growing use of cell therapy and other products derived from donated and stored tissues in biobanks, the issue of storing human tissues in biobanks remains contentious, particularly regarding its social implications (14). Society's acceptance of these banks, both as potential donors and recipients, plays a direct role in this (15). Additionally, since perspectives on various topics, including biobanks and their ethical challenges, are influenced by the cultural background of a given society, and research on this topic has predominantly been conducted in Western societies, exploring the viewpoints of specialists and users of the services offered by these banks within the Iranian context is deemed crucial. This necessitates a thorough examination of the social, ethical, and legal dimensions of umbilical cord blood banking (16, 17).

2. Objectives

Given these considerations, it is evident that umbilical cord blood banking presents ethical dilemmas, with many of these challenges rooted in sociocultural issues. Therefore, this study was designed to explore these challenges from the perspectives of those involved in the biobank processes within the Iranian community.

3. Methods

3.1. Purpose

The aim of this research is to elucidate the ethical challenges associated with umbilical cord blood stem cell banking.

3.2. Design

This qualitative study employs conventional content analysis. Data collection was carried out through semi-structured interviews, with the researcher actively engaged in the research process to capture the complexity and nuances of the topic under investigation (18).

Table 1. Demographic Characteristics of the Participants

| Row | Participant | Age, y | Gender |
|-----|--|--|--------|
| 1 | Subspecialist in hematology, pediatric oncology, and umbilical cord blood transplant | 53 | Male |
| 2 | Specialist in medical ethics | 50 | Male |
| 3 | Supervisor of umbilical cord blood stem cell banking | 38 | Male |
| 4 | PhD in law | 40 | Male |
| 5 | Subspecialist in hematology, pediatric oncology, and umbilical cord blood transplant | 52 | Male |
| 6 | PhD in law | 39 | Male |
| 7 | Doctorate in Islamic jurisprudence and law | 53 | Male |
| 8 | Midwife | 39 | Female |
| 9 | Specialist in umbilical cord blood stem cell banking and transplant | 42 | Female |
| 10 | Medical geneticist | 53 | Male |
| 11 | Supervisor of umbilical cord blood stem cell transplant | 36 | Female |
| 12 | Family 1 | Father of child diagnosed with ALL | Male |
| 13 | Family 2 | Father of a child diagnosed with aplastic anemia | Male |
| 14 | Family 3 | Father of child diagnosed with thalassemia | Male |

3.3. Participants

The participants were chosen through purposive sampling. Efforts were directed at including representatives from all umbilical cord blood banks based on their size and area of expertise, as well as specialists knowledgeable about the subject and eligible families.

Specialists across various relevant fields were invited for interviews, encompassing medical ethics experts, health policymakers, professionals in umbilical cord blood storage, midwives, specialists in umbilical cord blood transplantation, geneticists, lawyers, and religious scholars with a minimum of three years of experience dealing with umbilical cord blood issues, alongside the families of donors and recipients (Table 1).

3.4. Data Collection

Participants were informed about the research goals, and consent was obtained to record the interviews.

Interviews commenced with the primary question, “In your opinion, what are the ethical challenges of umbilical cord blood banks?” Follow-up questions were posed as needed to encourage interviewees to provide additional or clarifying information. Interviews ranged from 35 to 70 minutes. Data saturation was achieved after conducting interviews with 11 specialists and three families.

To enhance the quality of the findings, we adhered to Lincoln and Guba’s criteria (19). Research credibility was bolstered by applying the principle of diversity in sampling, choosing participants with varied demographic characteristics, such as field of expertise, age, and gender. At the conclusion of the interviews, a brief summary of the researcher’s overall understanding of the participants’ statements was shared, and participants verified this summary. For confirmability, the analysis and findings were reviewed by four renowned qualitative researchers and five medical ethics experts. Following their feedback, adjustments were made while preserving the authenticity of the data and findings. All raw data and notes were retained for potential future examination. To ensure dependability, colleagues participating in the study were briefed on the analysis and coding processes and shared their insights during scheduled discussions. The themes, categories, subcategories, and meaning units were solidified with the consensus of all authors. A substantial number of direct quotes from participants’ statements were included.

3.5. Statistical Analysis

Data were organized and analyzed using MAXQDA 2018 software, following the Graneheim and Lundman methods. Initially, the researcher conducted the first interview and, with the assistance of a research colleague, transcribed it on the same day. Subsequently, the transcription was meticulously reviewed by the researchers to gain an overall understanding. Then, all interview transcripts were thoroughly read, and meaningful units were identified. In the next phase, codes sharing similar meanings and concepts were grouped under a single subcategory, and their interrelations were established. Following this, the codes and subcategories were organized into main categories, which were conceptually broader and more abstract, leading to the extraction of themes. A collaborative meeting was convened to discuss the data analysis process, during which feedback from all colleagues was incorporated.

3.6. Ethical Considerations

Participants were thoroughly informed about the research objectives, the confidentiality and anonymity of

their information, the non-disclosure of their identities in the research findings, and their informed consent was obtained. The research was registered with the ethics code IR.SBMU.REC.1400.014.

4. Results

Table 1 shows the demographic characteristics of the participants.

The majority of study participants were male and possessed professional doctorates.

The insights gained from the interviews were divided into five primary themes, along with categories and subcategories, as follows (Table 2):

4.1. Theme 1: Information Presentation

It includes the categories “Informed Consent” and “Information Communication and Advertising.”

4.1.1. Category 1: Informed Consent

This category encompasses three subcategories: receiving information, obtaining informed consent, and the disclosure of relevant information. Some experts opposed the notion of obtaining informed consent, arguing that since umbilical cord blood is either discarded or stored without charge in cases of donation, obtaining informed consent was deemed unnecessary. Conversely, a faction of proponents argued that informed consent is crucial, especially in private banks, to formalize a contract between the parties and ensure adherence to its terms.

M1: “We recover the cells from the placenta –a placenta that is discarded. So, getting consent for this is useless.”

M3: “I don’t think merely obtaining informed consent is enough. Informed consent must be based on complete awareness and accurate information.”

M11: “In practice, there is no such thing as informed consent, because not all the facts and steps of the process are fully explained due to different reasons, either on the part of the doctors or the umbilical cord blood banks.”

4.1.2. Category 2: Information Communication and Advertising

This category is divided into two subcategories: “information communication” and “advertising.” Some participants expressed concerns over the advertising strategies of private banks, which they believed often convey exaggerated claims about the effectiveness and potential uses of stored blood, failing to provide accurate and decisive information to the public.

M2: “But accurate information must be communicated, and it is somewhat misleading to say that donating blood is donating life or an investment

Table 2. Summary of the Themes and Subthemes

| Theme | Category | Subcategory |
|---|---|--|
| Information presentation | Informed consent | Receiving information |
| | | Obtaining informed consent |
| | | Providing proper information |
| | Information communication and advertising | Communicating information |
| Advertising | | |
| Interpersonal relations of those involved | Financial issues | Cost of receiving cells |
| | | Cost of banking cells |
| | | Financial ties with banks |
| | Conflicts of interest | Conflicts of interest in opening blood banks |
| | | Conflicts of interest in using blood banks |
| | Professional relations | Relations between the recipients and the blood banks |
| | | Relations between the physicians |
| | | Relations between the physicians and the blood banks |
| | Human dignity | Ownership of the child and parents |
| Ownership options | | |
| Confidentiality and privacy | | Information Confidentiality |
| | | Information security |
| | | Human dignity |
| Regulations and guidelines | Rules and regulations | Monitoring the blood banks' activities |
| | | Laws |
| | Guidelines | Ethical guidelines |
| | | Ethical supervision and approval |
| Use of tissue samples | Clinical applications | Cell transplant complications |
| | | Donor screening and testing |
| | | Cell performance |
| | Research applications | Animal studies |
| | | Research application |

to save the future. We must not mislead the audience to make false assumptions.”

The manner in which umbilical cord blood banks are advertised poses another challenge in this realm.

M3: “The advertising by private banks has made people

spend money on them.”

M10: “The lack of clarification by the healthcare sector and the advertisements claiming that several people have been cured with stem cells and umbilical cord blood are also not right. It is incorrect to present them as the main and final treatment and say that umbilical cord blood treats diseases fully.”

M3: “The next issue is how we present facts in advertising. Some of the information provided by organizations to attract clients is not that correct or is exaggerated.”

4.2. Theme 2: Interpersonal Relationships of Those Involved in the Process

This theme covers three categories: financial matters, conflicts of interest, and professional relationships.

4.2.1. Category 1: Financial Issues

This category comprises three subcategories: the cost of cell collection, the cost of cell storage, and financial relationships with the banks. Challenges highlighted, particularly by recipient families, include the high costs of transplants and travel for those residing far from the capital, complicating access to stem cells and cell banks. Moreover, the expense of storing cells can deter many from continuing with cell storage in blood banks amidst financial hardships.

F1: “We had issues with the high costs of the transplant because we had to go to Tehran 15 to 20 times. Each trip costs a lot.”

F2: “Storing the cells in the bank costs a lot, and we have to pay some money for their storage each year. With the inflation being what it is, we may not be able to store the cells for our child.”

M5: “If a contract is signed with the bank, you can get paid for it.”

4.2.2. Category 2: Conflicts of Interest

This category encompasses subcategories concerning conflicts of interest in the management of blood banks and in utilizing the blood banks. Conflicts of interest represent a significant hurdle in umbilical cord blood banks, arising occasionally when the bank’s founder is also a physician performing transplants.

M2: “Many umbilical cord blood bank managers are also physicians. Considering their area of work in healthcare, the issue of conflicts of interest was also mentioned as a challenge of these banks.”

M6: “Sometimes I think some of the doctors get paid a commission by some of the banks to send them samples. I see people bring in the samples with no comprehension of

their benefits. When I ask why, they say the doctor insisted that we bring it to you.

M6: "It is not clear to people and even many of those working in this area how the bank profits are used and this is a great ethical challenge.

4.2.3. Category 3: Professional Relations

This category is divided into three subcategories: relationships between the recipients and umbilical cord blood banks, relationships among physicians, and relationships between physicians and the banks. The interviews indicated that relationships between physicians and both public and private umbilical cord blood banks should be transparent during the informed consent process. Physicians should not receive financial or other incentives for sample collection, and there should be no contact between the donor and recipient to prevent ethical and financial complications.

M8: "The path to health depends on responsible individual actions. The relations between the patient and physician and public and private medical companies active in modern medicine evolve by defining and expressing interests and they act as an intermediary for the transfer of information and the services provided by these companies to the clients."

4.3. Theme 3: Human Dignity

This theme includes the two categories of ownership by the child and parents, as well as privacy and confidentiality.

4.3.1. Category 1: Ownership and Confidentiality

This theme is broken down into categories concerning ownership by the child and parents, and privacy and confidentiality. It includes subcategories on ownership rights and options.

Specialist groups hold differing views on the ownership of umbilical cord blood. Some argue that there is essentially no ownership, while others acknowledge ownership but with varying perspectives. Those advocating for ownership cite examples like the mother's right to donate or store the cord blood, considering it an embryonic product. Another viewpoint grants this right to the child, suggesting a decision should be made upon reaching legal age. Yet, others believe the decision belongs to both parents as a couple. A few even contend that financial considerations give exclusive decision-making rights to the family's father. It's important to note that ownership discussions are primarily legal rather than medical or ethical, with most lawyers recognizing authority over the embryonic product rather than outright ownership rights.

M5: "Basically, human products cannot be owned. The expression used for it in the law is 'authority to make a decision,' not 'ownership.' In other words, there is a right, but not of ownership, because human products are not a property for which to envisage ownership."

M7: "But the decision-maker for donation is the person himself when he grows up."

M1: "In my view, umbilical cord blood is not solely in the ownership of the mother simply just because it is part of the birth. Since financial decisions are generally made by the father, he has sole authority and the mother has nothing to do with the matter, but the easiest way is to say that both [are in charge]."

P3: "If the child is in a decision-making position, the blood belongs to them."

4.3.2. Category 2: Privacy and Confidentiality

This category is divided into three subcategories: information confidentiality, information security, and human dignity. Some experts argue against the anonymity of the blood donor and their family and the non-disclosure of their blood data, emphasizing that the donor or a family member might need the blood in the future, thus highlighting the importance of easy tracing and retrieval of the patient's information. Private banks argue that saving this information with the patient's name will ease access and retrieval when necessary. However, there is a consensus that such information should not be universally accessible to prevent misuse.

M5: "Whether the blood data can be accessed or not depends on the bank and type of contract. If the aim is to store the blood, then it must definitely be under a name, and the cost must also be paid. In this case, it is accessible."

M2: "The confidentiality of the donors' and recipients' information must be maintained in public and private banks. It is only with confidentiality and anonymity that ethical issues can be kept under control."

4.4. Theme 4: Rules and Regulations

This theme encompasses two categories: regulations and solutions.

4.4.1. Category 1

Regulations, which are further divided into subcategories focusing on monitoring blood bank activities and establishing rules. Interviewees pointed out that the absence of effective regulations sometimes leads to ethical challenges. Blood banks are expected to possess the necessary permits, adhere to their articles of association, and follow clear guidelines and regulations that avoid exaggeration. They should also clearly define the terms of contracts, commercialization, and donorship.

M5: "The banks must have certain permits in their articles of association and specify certain codes in them. Commercialization and contracts must be concluded in an informed manner in order to be considered valid. They must not include exaggeration or be misleading. If they entail lies, the contract can be terminated."

M1: "Rules and guidelines are always subject to change and misuse. We must have a framework for updating them in order to prevent their misuse."

Concerns were raised about individuals potentially missing out on transplants due to unclear regulations and possible financial challenges at the time of the transplant.

M1: "All people must have equitable access to umbilical cord blood banks."

4.4.2. Category 2: Guidelines

This category encompasses two subcategories: ethical guidelines, and ethical supervision and approval. The term "guideline" refers to a general rule, principle, or piece of advice. One of the challenges identified from the interviews is the lack of efficient ethical guidelines in this field.

M8: "At times when there is a difference of opinions, having ethical guidelines in place can help and clear up the situation."

M2: "It would be extremely helpful if the decisions made can be ethically approved by a committee or something similar and if there is ethical supervision. This can set a precedence for future decision-making."

4.5. Theme 5: The Use of Tissue Samples

This theme is divided into two categories: clinical application and research application.

4.5.1. Category 1: Clinical Application

This category includes three subcategories: complications of cell transplants, donor screening and testing, and cell performance.

Some specialists are skeptical about expanding umbilical cord blood banks and storage, citing concerns over the unproven cost-effectiveness of storage and questioning its feasibility. Others argue that stored blood represents a critical treatment option for some patients, suggesting a cautious expansion of banks. Conversely, given the high costs associated with importing blood, some advocate investing in the expansion of domestic blood bank storage. A significant concern for families considering storage is whether the banked blood will prove beneficial for treating potential diseases in the future. Families who have stored umbilical cord blood stem cells with informed consent and subsequently

donated it—despite the donation being voluntary—have expressed worries about potentially needing the blood for themselves or their children in the future.

F1: "Our first child had thalassemia, and when we had a second one on the way, we were worried about the cost of storing the blood of the second baby and whether this would be useful for the first baby or not."

F3: "We were under the impression that the umbilical cord blood is useful and can treat many diseases, but later, we found that although it has many uses, it can be controversial in some cases. Since we don't know exactly which diseases can currently be treated with this blood."

F3: "We were also worried about complications at the time of the transplant, but since it was the only solution, we had to accept it. Thank God we got positive results, but we were worried because we had no idea how it would turn out."

M6: "Stem cells do not have the same usage as they did over the past decades. We must understand that if it is not useful, we should not expand the banks and invest more."

4.5.2. Category 2: Research Application

Umbilical cord blood cells are recognized as a valuable resource for conducting related research, including both human and animal studies. Hence, this category includes two subcategories: animal studies and use in human research.

M7: "Some of the difficulties faced by the families include that whether these cells will be used in research. For instance, some people don't like it that their child's umbilical cord blood cells be injected into mice or guinea pigs."

M6: "Right now, they are working on the cells recovered from umbilical cord blood. They are researching to see if these can be used in certain diseases or not."

5. Discussion

This qualitative study aims to elucidate the ethical challenges associated with umbilical cord blood stem cell banks. The principal themes emerging from interviews with both specialists and families encompass the presentation of information, interpersonal relationships among stakeholders, respect for human dignity, adherence to rules and regulations, and the use of tissue samples.

The data gathered from participants indicate the necessity for families to be comprehensively informed about umbilical cord blood banks and storage processes prior to providing their informed consent. Concerns were raised about the absence of clear procedures for obtaining

informed consent for blood donation and the lack of dedicated authorities to address this issue. Corresponding to these findings, the challenge of securing informed consent for donating or storing umbilical cord blood was also highlighted in the study by Ozturk Turkmen and Arda (20). Furthermore, Rao et al. emphasized the importance of individuals being informed about the processes involved in the collection and use of donated blood, either for themselves or for others, and providing their explicit consent for these procedures (21).

The practice of securing individuals' consent and informing them about their participation has been longstanding (22). Within the framework of laws regulating the tissue economy, the contractual agreement (inclusive of an informed consent clause) should encompass a broad spectrum of scenarios, ranging from tissue donation to storage for personal use (23).

Another significant ethical concern involves ensuring equitable access to the services offered by these banks (24). Ethically, it is imperative that individuals can readily utilize these banks' services when necessary. However, in reality, many people face challenges in storing their samples in private banks due to various reasons, including financial constraints. Additionally, there may be lengthy waiting lists for accessing the services of public blood banks, potentially posing a threat to life (25). The interviews highlighted challenges such as the high costs associated with transplants, particularly travel expenses for those residing outside the capital. Umeh and Feeley found that individuals with limited financial resources and no insurance are more vulnerable to diseases and often prioritize spending on essentials like food and shelter over healthcare, leading to reduced access to medical services, which contradicts ethical principles (26). The establishment of private umbilical cord blood stem cell banks aims to offer superior services to those who can afford them (27). Health policymakers are tasked with not only facilitating quicker access to services for those willing to pay but also improving the availability and conditions of public umbilical cord blood bank services for the broader population (28).

The issue of umbilical cord blood ownership and determining who holds authority over it presents another challenge. The current study highlights a lack of consensus regarding the ownership of umbilical cord blood. Opinions vary, with some advocating for maternal ownership, others for paternal ownership, and still others believing that both parents share ownership. Mendes-Takao et al. and Chima and Mamdoo supported the view that the mother has ownership rights over the umbilical cord blood as it is considered a product of birth (22, 29). Conversely, research by Pinch, Warwick and

Fehily, and Childress. suggests that ownership should reside with the parents, while some argue that the child should make decisions regarding their stored blood upon reaching puberty. Furthermore, findings indicate that the storage of samples in private umbilical cord blood banks is initiated upon request by the applicant and funded through payment, making the applicant or contract party the owner of the sample (30, 31). Childress noted that in public umbilical cord blood banks, samples are donated by families, storage is offered free of charge, and any ownership rights are held by the public bank (24).

Several studies propose that in private banks, parents hold ownership of the umbilical cord blood until the child reaches 18 years of age. Ownership then passes to the child on the condition they continue paying for storage. Failure to cover these costs results in the loss of ownership rights for the child (23). Consequently, some U.S. laws associate ownership with the capacity to sustain payment obligations.

According to some legal experts, umbilical cord blood and its components are the property of the mother, and any use of it requires her consent. Conversely, others argue that the blood is not solely the mother's but is shared with the infant. They assert that the infant's ownership, similar to their other financial assets, is established through legal guardianship (32).

Another major challenge facing umbilical cord blood banks is the existence and enforcement of ethical rules and guidelines within different countries. Evidence from various parts of the world indicates a widespread failure to adhere to medical ethics, highlighting the need for stringent ethical regulations and oversight of umbilical cord blood banks (33, 34).

Advertising has also emerged as a significant challenge in this study. It is essential for advertisements to accurately communicate the potential benefits of private umbilical cord blood banks to clients and to make it clear that the likelihood of using the stored sample for autologous purposes is slim, and that certain future treatments may be inaccessible. Local authorities should regulate advertising practices (23).

Reviews of findings by Warwick and Fehily, and Torkaman et al. indicate that all advertising for umbilical cord blood banks should be prohibited. Blood banks must not present themselves as commercial entities or engage in practices that mislead individuals or incite fear through unscientific methods (31). The public deserves accurate information regarding the pros and cons of umbilical cord blood banks. The content of advertisements or information provided to families must be precise, and informed consent must be secured from them before storing their infant's umbilical cord blood (35).

Financial issues and commercialization represent another challenge discussed in this study, particularly regarding the extent to which these cells can be utilized. A significant ethical concern raised during the interviews and reflected in the study findings pertains to cloning. In line with the studies reviewed, there was considerable apprehension among families and specialists regarding the cloning, commercialization, and trading of umbilical cord blood (19, 29, 36).

International laws underscore that biological materials should not result in financial profit (37). Mendes-Takao et al. highlighted the insufficient oversight of bank procedures in their research (27). Numerous critics, including Panagouli et al., have associated the utilization of stem cells and umbilical cord blood with religious concerns, arguing that using these cells contravenes religious teachings. Additionally, these critics contend that the use of these cells should be highly restricted and that rigorous monitoring and legislation are necessary for their broader application (36).

The issues of confidentiality, privacy, and discretion, particularly whether the identities of donors and recipients should be revealed, especially in public umbilical cord blood stem cell banks, present another challenge identified in this study. This finding aligns with those of other research; for instance, Petrini asserted that service providers at these banks should endeavor to maintain the anonymity of users. However, the question remains as to whether donors of umbilical cord blood can be informed about the identities of the recipients (38). Ballen, and Mendes-Takao et al. stressed the importance of protecting personal information in these banks and noted that the decision to reveal or conceal this information at the donor's request has sparked considerable debate among proponents and critics of this practice. Despite differing views, there is a general agreement that umbilical cord blood banks must safeguard this information as private and confidential (29, 39).

The application of stem cells derived from umbilical cord blood in research holds the promise of addressing a multitude of previously untreatable conditions and alleviating human suffering. However, without adequate quality control, there is a risk that the medical commitment to "do no harm" could be compromised (23).

The Declaration of Helsinki strictly forbids exploiting individuals for research purposes and underscores the necessity of respecting individuals by safeguarding their autonomy through the process of obtaining informed consent. The practice of securing informed consent serves as a cornerstone of bioethics. While this principle alone does not safeguard individuals, it empowers them to exercise their fundamental right to decide on the

utilization of their body, body parts, and related products, particularly in research contexts (37).

5.1. Conclusions

In contemporary medicine, evidence-based clinical practices and technological advancements have opened new avenues for treating numerous diseases previously deemed incurable. The rapid evolution in stem cell transplantation exemplifies such progress. The findings from this study highlight that the operation of umbilical cord blood stem cell banks brings forth specific ethical challenges and concerns across various nations. Given the critical importance of healthcare activities and their impact on life quality and human dignity, it is imperative to confront and address the ethical dilemmas associated with these practices, encompassing prevention, diagnosis, and treatment. Consequently, health policymakers worldwide must prioritize identifying and addressing these ethical challenges before establishing umbilical cord blood banks.

5.2. Recommendations

In light of the findings from this research and acknowledging the existing umbilical cord blood banks in Iran, the formulation of ethical guidelines on this matter would be beneficial for health decision-makers. Furthermore, the inclusion of ethical experts in these centers would be advantageous, as they would offer necessary ethical advice, monitoring, and assessment.

Acknowledgments

This work was financially supported by the Shahid Beheshti University of Medical Sciences (Tehran, Iran) and approved by ethics in research committee (ethics code: IR.SBMU.REC.1400.014)

Footnotes

Authors' Contribution: M.S.G. wrote the manuscript; Sh.B.L.A. conceived the presented idea and reviewed the manuscript; Sh.B., L.A., M.F., M.K, and S.A.E. developed the concept and edited the manuscript; M.S.G. and Sh.B. developed the concept, performed the professional editing and reviewing, and approved the final version. All authors read and approved the final manuscript.

Conflict of Interests: The authors reported no conflicts of interest.

Data Availability: It was not declared by the authors.

Ethical Approval: Ethics code: IR.SBMU.REC.1400.014.

Funding/Support: This work was financially supported by a Grant (26777) from the Shahid Beheshti University of Medical Sciences (Tehran, Iran).

Informed Consent: The informed consent was obtained.

References

1. Abroon S. [Umbilical cord blood banking]. *Blood J*. 2013;**11**(3):270–5. Persian.
2. Waldby C, Mitchell R. *Tissue economies: Blood, organs, and cell lines in late capitalism*. 1st ed. New York, USA: Duke University Press; 2006. <https://doi.org/10.1215/9780822388043>.
3. Lenard PT. *Culture*. Stanford Encyclopedia of Philosophy; 2020. Available from: <https://plato.stanford.edu/archives/win2020/entries/culture/>.
4. Smith AR, Wagner JE. Alternative haematopoietic stem cell sources for transplantation: place of umbilical cord blood. *Br J Haematol*. 2009;**147**(2):246–61. [PubMed ID: 19796274]. [PubMed Central ID: PMC2782564]. <https://doi.org/10.1111/j.1365-2141.2009.07828.x>.
5. Rocha V, Kabbara N, Ionescu I, Ruggeri A, Purtill D, Gluckman E. Pediatric related and unrelated cord blood transplantation for malignant diseases. *Bone Marrow Transplant*. 2009;**44**(10):653–9. [PubMed ID: 19802021]. <https://doi.org/10.1038/bmt.2009.291>.
6. Brunstein CG, Weisdorf DJ. Future of cord blood for oncology uses. *Bone Marrow Transplant*. 2009;**44**(10):699–707. [PubMed ID: 19802022]. <https://doi.org/10.1038/bmt.2009.286>.
7. Prasad VK, Kurtzberg J. Umbilical cord blood transplantation for non-malignant diseases. *Bone Marrow Transplant*. 2009;**44**(10):643–51. [PubMed ID: 19802020]. <https://doi.org/10.1038/bmt.2009.290>.
8. Stewart C, Kerridge I. Umbilical cord blood banking and the next generation of human tissue regulation: an agenda for research. *J Law Med*. 2012;**19**(3):423–9. [PubMed ID: 22558895].
9. Querol S, Gomez SG, Pagliuca A, Torrabadella M, Madrigal JA. Quality rather than quantity: the cord blood bank dilemma. *Bone Marrow Transplant*. 2010;**45**(6):970–8. [PubMed ID: 20190835]. <https://doi.org/10.1038/bmt.2010.7>.
10. Jordens CF, O'Connor MA, Kerridge IH, Stewart C, Cameron A, Keown D, et al. Religious perspectives on umbilical cord blood banking. *J Law Med*. 2012;**19**(3):497–511. [PubMed ID: 22558902].
11. McKenna D, Sheth J. Umbilical cord blood: current status & promise for the future. *Indian J Med Res*. 2011;**134**(3):261–9. [PubMed ID: 21985808]. [PubMed Central ID: PMC3193706].
12. *Opinion No 42 of 16 April 2007 on umbilical cord blood banks*. Belgian Advisory Committee on Bioethics; 2007. Available from: https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/opinion_42_web_0.pdf.
13. Sugarman J, Reisner EG, Kurtzberg J. Ethical aspects of banking placental blood for transplantation. *JAMA*. 1995;**274**(22):1783–5. [PubMed ID: 7500510].
14. Lipworth W, Forsyth R, Kerridge I. Tissue donation to biobanks: a review of sociological studies. *Sociol Health Illn*. 2011;**33**(5):792–811. [PubMed ID: 21592141]. <https://doi.org/10.1111/j.1467-9566.2011.01342.x>.
15. Antonova N, Eritsyan K. It is not a big deal: a qualitative study of clinical biobank donation experience and motives. *BMC Med Ethics*. 2022;**23**(1):7. [PubMed ID: 35090454]. [PubMed Central ID: PMC8800256]. <https://doi.org/10.1186/s12910-022-00743-6>.
16. Gluckman E. History of cord blood transplantation. *Bone Marrow Transplant*. 2009;**44**(10):621–6. [PubMed ID: 19802032]. <https://doi.org/10.1038/bmt.2009.280>.
17. Katz G, Mills A, Garcia J, Hooper K, McGuckin C, Platz A, et al. Banking cord blood stem cells: attitude and knowledge of pregnant women in five European countries. *Transfusion*. 2011;**51**(3):578–86. [PubMed ID: 21126259]. <https://doi.org/10.1111/j.1537-2995.2010.02954.x>.
18. Speziale HS, Streubert HJ, Carpenter DR. *Qualitative research in nursing: Advancing the humanistic imperative*. Lippincott Williams & Wilkins; 2011.
19. Tesch R. *Qualitative research: Analysis types and software*. 3rd ed. New York, USA: Routledge; 2013.
20. Ozturk Turkmen H, Arda B. Ethical and legal aspects of stem cell practices in Turkey: where are we? *J Med Ethics*. 2008;**34**(12):833–7. [PubMed ID: 19043103]. <https://doi.org/10.1136/jme.2007.022806>.
21. Rao M, Ahrlund-Richter L, Kaufman DS. Concise review: Cord blood banking, transplantation and induced pluripotent stem cell: success and opportunities. *Stem Cells*. 2012;**30**(1):55–60. [PubMed ID: 22069231]. <https://doi.org/10.1002/stem.770>.
22. Chima SC, Mamdoo F. Ethical and regulatory issues surrounding umbilical cord blood banking in South Africa. *S Afr J Bioeth Law*. 2011;**4**(2):79–84.
23. Fannin M. Personal stem cell banking and the problem with property. *Soc Cult Geo*. 2011;**12**(4):339–56. <https://doi.org/10.1080/14649365.2011.574795>.
24. Childress JF. Sources of stem cells: ethical controversies and policy developments in the United States. *Fetal Diagn Ther*. 2004;**19**(2):119–23. [PubMed ID: 14764953]. <https://doi.org/10.1159/000075133>.
25. Sabone M, Mazonde P, Cainelli F, Maitshoko M, Joseph R, Shayo J, et al. Everyday ethical challenges of nurse-physician collaboration. *Nurs Ethics*. 2020;**27**(1):206–20. [PubMed ID: 31014168]. <https://doi.org/10.1177/0969733019840753>.
26. Umeh CA, Feeley FG. Inequitable Access to Health Care by the Poor in Community-Based Health Insurance Programs: A Review of Studies From Low- and Middle-Income Countries. *Glob Health Sci Pract*. 2017;**5**(2):299–314. [PubMed ID: 28655804]. [PubMed Central ID: PMC5487091]. <https://doi.org/10.9745/GHSP-D-16-00286>.
27. Dahlke S, Stahlke S. Ethical challenges in accessing participants at a research site. *Nurse Res*. 2020. [PubMed ID: 31916421]. <https://doi.org/10.7748/nr.2020.e1665>.
28. Millum J, Campbell M, Luna F, Malekzadeh A, Karim QA. Ethical challenges in global health-related stigma research. *BMC Med*. 2019;**17**(1):84. [PubMed ID: 31030670]. [PubMed Central ID: PMC6487527]. <https://doi.org/10.1186/s12916-019-1317-6>.
29. Mendes-Takao MR, Diaz-Bermúdez XP, Deffune E, De Santis GC. [Private umbilical cord blood banks for family use, in Brazil - technical, legal and ethical issues for an implementation analysis]. *Rev Bras Hemat Hemot*. 2010;**32**(4):317–28. Portuguese. <https://doi.org/10.1590/s1516-84842010005000090>.
30. Pinch WJ. Cord blood banking: ethical implications. *Am J Nurs*. 2001;**101**(10):55–9. [PubMed ID: 11680345]. <https://doi.org/10.1097/00000446-200110000-00027>.
31. Warwick R, Fehily D. Ethics of cord blood banking. *Curr Obstet Gynaecol*. 2002;**12**(3):175–7. <https://doi.org/10.1054/cuog.2001.0255>.
32. Mohajer Milani A. The Ownership of Stem Cells in the Umbilical Cord Blood. *Relig Res*. 2017;**13**(3):655–86. <https://doi.org/10.22059/jorr.2017.214441.1007425>.
33. Bollen JAM, Shaw D, de Wert G, Ten Hoopen R, Ysebaert D, van Heurn E, et al. Euthanasia through living organ donation: Ethical, legal, and medical challenges. *J Heart Lung Transplant*. 2019;**38**(2):111–3. [PubMed ID: 30197210]. <https://doi.org/10.1016/j.healun.2018.07.014>.
34. Carlisle EM, Rowell EE. Ethical challenges in regionalization of pediatric surgical care. *Curr Opin Pediatr*. 2019;**31**(3):414–7. [PubMed ID: 31090585]. <https://doi.org/10.1097/MOP.0000000000000764>.
35. Genovese F IV, Carbonaro A MI, Leanza G VS. Umbilical Cord Blood Collection: Ethical Aspects. *Gynecol Obstet*. 2012;**2**(3). <https://doi.org/10.4172/2161-0932.1000121>.
36. Panagouli E, Dinou A, Mallis P, Michalopoulos E, Papassavas A, Spyropoulou-Vlachou M, et al. Non-Inherited Maternal Antigens Identify Acceptable HLA Mismatches: A New Policy for the

- Hellenic Cord Blood Bank. *Bioengineering (Basel)*. 2018;**5**(4). [PubMed ID: 30248919]. [PubMed Central ID: PMC6316301]. <https://doi.org/10.3390/bioengineering5040077>.
37. Cambon-Thomsen A, Rial-Sebbag E, Knoppers BM. Trends in ethical and legal frameworks for the use of human biobanks. *Eur Respir J*. 2007;**30**(2):373-82. [PubMed ID: 17666560]. <https://doi.org/10.1183/09031936.00165006>.
38. Petrini C. Ethical issues in umbilical cord blood banking: a comparative analysis of documents from national and international institutions. *Transfusion*. 2013;**53**(4):902-10. [PubMed ID: 22845856]. <https://doi.org/10.1111/j.1537-2995.2012.03824.x>.
39. Ballen K. Challenges in umbilical cord blood stem cell banking for stem cell reviews and reports. *Stem Cell Rev Rep*. 2010;**6**(1):8-14. [PubMed ID: 19997789]. <https://doi.org/10.1007/s12015-009-9105-x>.