A COMPARITIVE ANALYSIS OF LEGAL ISSUES WITH UMBILICAL CORD BLOOD COLLECTION AND STORAGE

Kavya G, LLM (Medical and Health Law) student, Department of Law, Amity Law School, Noida, Amity University, Noida (Uttar Pradesh)
Prof. (Dr.) Meenu Gupta, Professor,Department of Law, Amity Law School, NoidaAmity University, Noida (Uttar Pradesh)

Abstract
Umbilical cord was considered as a medical waste during the earlier time. After identifying the medical value of umbilical cord blood it is no longer considered as a medical waste. Umbilical cord blood contains potential stem cells which have the ability to divide into various adult cells so that it is a great source for treating life endangering diseases like cancer and other blood related diseases like anemia and immune disorder. For all these cord blood should be collected properly and safely so that the viability of the stem cells contained in it is not lost and cord blood is not get contaminated. This had raised the need for establishing cord blood banks where the cord blood are collected, processed and stored. This emergence of blood banks had need to enactment of proper laws which regulates the establishing and functioning of this banks but there is issue with regard to every aspects of umbilical cord blood collection across the world as there is lack of proper law which regulates this part and also the regulations which already exist are ambiguous with various provisions which create legal issues with the collection and storing of cord blood. Thus this article is a comparative analysis of legal issues of different countries with umbilical cord blood collection and storage.
Keywords: Umbilical Cord**,** Umbilical Cord Blood, Umbilical Cord Blood Bank, Public Cord Blood Bank, Private Cord Blood Bank, Umbilical Cord Blood Collection Procedure.

Introduction

Life is the condition of being alive as well as the events and circumstances that accompany existence and surviving as a living entity. It includes individualized social, emotional, and spiritual aspects as well as biological processes as cellular growth, reproduction, metabolism, and response to stimuli. In the end, the meaning and purpose of existence are purely arbitrary and subject to philosophical, religious, and scientific debate. Now umbilical cord blood is considered to be one of the life saving element as it a rich source of stem cell with can regenerate itself so which can be used to treat various serious diseases.

Umbilical cord blood, rich in hematopoietic stem cells, that is capable to regenerate to different adult cells like muscle cells, blood cell, brain cells etc... Since cord blood are valuable as they are life saver because it has emerged as a valuable resource in medical treatments and research which has shown immense potential in treating various life- threatening diseases. Therefore the cord blood has to be collected and stored so that it can be used when any need arise in future. This need for preservation of cord blood lead to the concept of cord blood banking after the first successful umbilical cord blood stem cell transplant performed in Paris, France in the year 1988 after which more than 35000 such similar process were conducted across the world by considering variance towards indications.

The procedure of obtaining cord blood after delivery along with preserving blood from umbilical cord for future use is termed as umbilical cord blood banking This has gained popularity world wide by the mid twentieth century due to the presence of hematopoietic stem cell in the cord blood which is used as an alternative to bone marrow for the treatment of various diseases like cancer, other blood related diseases like anemia and other immune system disorders which inhibits the body's capability to protect itself. First establishment of cord blood bank was in the year 1992 at the New York Blood Centre which was a public cord blood bank and were funded by the National Institute of Health , USA which emerged as the new era of hope for who suffer in need of hematopoietic stem cell. First public cord bank in India was established in the year 1995 named Jeevan in Chennai, Tamil Nadu.

The collecting and examination of umbilical cord blood has gained importance in the area of medical law because the collection of umbilical cord blood raises several legal issues. For example, there are questions about who owns the rights to the blood. Some hospitals and birthing centers have

policies that give ownership of the umbilical cord blood to the institution, rather than the parents. thus this article deals with comparative study of legal issues faced by various countries.

STATEMENT OF PROBLEM

Umbilical cord blood is rich source of stem cell. Stem cells are valuable because they hep treat many life threatening diseases. In case of healthy people stem cell production is not a problem but unfortunately due to some medical condition or diseases some people may not be able to produce enough healthy stem cells therefore the cord blood collected can be used as a life saver for these people.The study is to analyse legal issue faced by various country with regard to umbilical cord blood collection and storage.

OBJECTIVE OF THE STUDY

- To study about various laws that regulate umbilical cord blood collection and storage across the world.
- To make a comparative analysis of various laws of different country with India related to umbilical cord blood collection and storage.
- To study about various legal issues with regard to umbilical cord blood collection and storage.

REVIEW OF LITERATURE

A literature review covers information that has been published in a specific field of study, and occasionally information that has been published within a specific time frame.A literature review can just be a synopsis of the source, but most of the time it combines both summary and synthesis and follows an organizational structure. The literature review may assess the sources and advise the reader on which are most topical or relevant, depending on the circumstance. A useful reference for a particular topic is provided by a literature review. However, the goal of a literature review is to synthesis and summaries the claims and theories of others without making any original additions. Numerous academics and writers from many different nations have studied the collection of umbilical cord blood and examined its moral and ethical implications. Some of the evaluations are as follows:

- Fernandez (1998): The specifications should be based on standards that have already been developed for the transfusion of whole blood and other non-frozen blood products. One of the many biological waste products that were dumped after a baby was born was cord blood.
- Moise.K.J (2005): The regulation of umbilical cord blood banking is woefully lacking. The standard of the transplantable specimen is impacted by the lack of quality control. Although some cord blood banks have voluntarily filed for accreditation, the accreditation procedure differs from bank to bank, public or private.
- The American Academy of Pediatrics(AAP) Policy Statement (Pediatrics2007;119:165-170): The report encourages parents to donate to public cord blood banks and discourages parents from using private cord blood banks for personal or family cord blood storage unless they have an older child with a condition that could benefit from transplantation. This recommendation is just one of many made in the report.
- Gunning (2007): Over the years, clinical transplants of bone marrow stem cells have been used to treat diseases. Although they were often thought to be a byproduct of childbirth, umbilical cord blood stem cells are now understood to contain up to ten times as many stem cells as adult bone marrow.
- McGuckin & Forraz(2008): The first public umbilical cord blood bank was established in New York in 1991 following the first reported cord blood stem cell transplant.
- Dinc H. and Shin N.H.(2009): To ascertain the knowledge of pregnant women, they conducted an exploratory descriptive study with 334 of them, gathering information through interviews. The survey found that the vast majority of participants sought additional information about stem cells and cord blood banking and had little expertise of these topics.
- Lawrence S.B. Goldstein and Meg Schneider(2010) :Despite the enormous potential benefits of stem cell research, it is clear that there are grave legal, moral, and ethical issues. Although these worries only apply to the use of ESC, they are nonetheless stoked by some of the most heinous

episodes in the annals of science and humanity. History has demonstrated that man is remarkably capable of using and abusing science to save and take lives. As an illustration, botulinum toxin [Botox] is frequently utilized in medicine for a range of medical disorders and has significant advantages. The fact that two kilogram mes of the same toxin, which is the most lethal material known to man, can obliterate the entire human race, however, has turned it into a bio-terrorist weapon! Medical research ought to follow strict medical ethical rulesand legislation, in order to stop misuse.

RESEARCH METHODOLOGY

The most popular approach used by law researchers for doctrinal research is library-based analysis. As is well known, this is theoretical research that consists of either basic research aimed at locating a particular legal argument or legal study with more distinct reasoning and depth.

Doctrinal research methodology refers to the systematic approach to studying doctrine or religious principles to gain an understanding of religious belief systems. This type of research involves analyzing and interpreting religious texts, examining the beliefs and practices of various religious groups, and reviewing literature related to a particular theology or religious doctrine.

The doctrinal research methodology usually involves the following

The researcher needs to identify the topic of interest in religious doctrine or theology that they wish to study. Involves collecting data through various sources such as religious texts, literature reviews, interviews, surveys, and observation. Once the data has been collected, it needs to be analyzed using an appropriate method that can help in identifying the religious beliefs or principles being studied. The data analysis stage is followed by interpretation, which involves drawing inferences and conclusions from the data collected. The final stage involves evaluating the data and findings to ensure that the research question has been answered satisfactorily.

In conclusion, the doctrinal research methodology is an essential tool for gaining an understanding of religious belief systems. It helps to analyze and interpret religious texts, examine the beliefs and practices of various religious groups, and review literature related to a particular theology or religious doctrine.

The research methodology adopted here is comparative doctrinal research. An approach used to analyse religious, legal, or philosophical doctrines is known as comparative doctrinal research. It entails comparing and analysing many doctrines or belief systems to find commonalities, discrepancies, and underlying principles. A thorough knowledge of the particular beliefs being researched is necessary for comparative doctrinal study, as is the capacity to evaluate and interpret the sources. It can offer insightful knowledge on the complexity and diversity of human thought and belief systems.

UMBILICAL CORD

During pregnancy umbilical cord connects baby to the mother’s placenta. It acts as a lifeline as it carries the oxygen, nutrients and other required elements for the growth baby and also helps in removing waste products that baby produce. A flexible tube-like structure called the umbilical cord joins a growing foetus to the placenta in the mother's uterus. Two arteries and one vein in the cord deliver oxygen- and nutrient-rich blood to the foetus from the placenta and eliminate waste from the body of the growing child. After the infant is born, the umbilical cord—which is normally 50–60 cm long and 2 cm wide—is usually severed. This umbilical cord is clamped and cut soon after the delivery of the baby.

UMBILICAL CORD BLOOD

Blood that persist in the placenta and umbilical cord after the infant is delivered is known as umbilical cord blood. One it was considered as medical waste is now collected, preserved and stored as it is a rich source of stem cells which is used for treating genetic disorders, immune deficiencies and cancers. Cord blood contains two type of stem cells hematopoietic stem cell as well as mesenchymal stem cells. But cord blood is the major source of hematopoietic stem cell which have the ability to generate into brain cell, skeletal muscle cell, cardiac muscle cell and liver cell and is used as a source for treatment of various diseases. Stem cells, which can differentiate into a variety of bodily cells, including red and white blood cells, platelets, are abundant in umbilical cord blood.

In particular, it comprises endothelial progenitor cells that maintain and repair blood vessels, hematopoietic stem cells that produce blood cells, and mesenchymal stem cells that can give rise to bone, cartilage, and other tissues.

Umbilical cord blood contains a wide range of other crucial cells and compounds in addition to stem cells, including as T cells, B cells, natural killer cells, cytokines, growth factors, and enzymes. These elements help to control the immune system, encourage tissue growth and healing, and ward off infections.

Another potential source of genetic material for research is umbilical cord blood.the discovery of novel treatments for hereditary diseases. Researchers can find genetic changes that may be connected to certain diseases and create targeted medicines to address them by examining the DNA and RNA present in cord blood.Overall, umbilical cord blood is a useful tool for medical investigation and the creation of novel medicines for a variety of ailments.

This blood is collected immediately when the umbilical cord is cut after the delivery of the baby. Stem cells are extracted from this collected cord blood are preserved and stored in the cord blood bank. This cord blood bank are of two type one which is private and the other which is public. Former is the blood donor center where this blood is stored as per the instruction of the donors and can be availed only by the donor family and relatives and is expensive too whereas the later can be accessed by the general public according to the need and matching of the patient and is not expensive.

Usually this stem cell is used for treating diseases like cancer such as leukemia and lymphoma, bone marrow diseases which requires transplant, sickle cell anemia as well as certain immune disorder. Recently research is being conducting to find out whether this stem cells can be used for treating parkinson’s disease and diabetes.

Even though stem cell has lot of value and are used widely for treatments still there is no proper law and regulations which is to be followed while collecting, preserving and delivering this stem cell. Therefore this study is conducted to get knowledge about the privacy of the donor, about consent from donor , about the use of stem cell by public other than the donor and their relatives, current situation in India and need of separate law to regulate cord blood banks.

UMBILICAL CORD BLOOD BANK

A institution that collects and preserves umbilical cord blood for potential use in future medical procedures is known as an umbilical cord blood bank. After a baby is born, the placenta and umbilical cord still contain blood, which is known as cord blood. This blood includes stem cells that can be used to treat a number of illnesses, including as leukaemia, lymphoma, and genetic problems. The cord blood is collected by the cord blood bank and is then frozen for use in the future, either by the baby's family or in clinical trials.

There are two kinds of banks for umbilical cord blood:

Public cord blood banks: These institutions gather contributions of cord blood from the general public and make it accessible to anyone in need of a transplant. People who do not have access to or cannot afford to pay the costs associated with private cord blood banks use public cord blood banks.

Private cord blood banks: These banks charge a fee to preserve cord blood, and the blood is only available to the family who kept it. Families with a history of genetic disorders or who are at high risk for specific illnesses frequently use private cord blood banks.

IMPORTANCE OF UMBILICAL CORD BLOOD BANKING

A growing number of parents are saving newborn child stem cells through cord blood banking, which may one day be utilized to treat a range of ailments. Some of the factors that make cord blood banking crucial are the ones listed below:

1. Potential medical advantages: Leukaemia, lymphoma, and other blood disorders are only a few of the ailments that can be treated with stem cells. Additionally, some inherited diseases including sickle cell anaemia and thalassemia may be treated by stem cells.

. Family advantages: Keeping cord blood can assist both the immediate family and the extended family, who may be more likely to inherit illnesses that are similar.

3. Cost savings: Cord blood banking only requires a single outlay of money.that has the potential to be a useful asset in the future. It can protect families from having to pay for costly medical procedures that may be necessary to treat a number of diseases.
4. Global accessibility: By preserving samples from all over the world in cord blood banks, stem cells are made accessible to anyone in the world who needs a transplant.
5. Research focus: A variety of medical disorders have been helped by the use of stem cells from cord blood in lengthy research investigations. People who donate cord blood to a public bank support scientific advancement and research.
Cord blood banking is viewed as an investment in the health and welfare of future generations, to sum up. It is a powerful tool that has the ability to save and enhance the lives of countless people.for any family expecting a kid, a great alternative.

ADVANTAGES AND DISADVANTAGES OF UMBILICAL CORD BLOOD STEM CELL
ADVANTAGES
- Effortless collection
- There is no risk to the mother or the kid iii. Processing takes less time, making the results more immediately usable.
- Bone marrow collection is more affordable.
- Lower risk of infection transmission.
- Mature cells in bone marrow have less of a need for precise HLA typing.
- Rejection of the graft is more unlikely.

DISADVANTAGE
- Decreased engraftment rate
- Its application is restricted to youngsters due to the inoculum's low cell dosage.
- Small unit's volume
- No more available cell dosages.
- Problems with storage at very low temperatures and associated costs

UMBILICAL CORD BLOOD COLLECTION PROCEDURE
The hospital must make sure that cord blood is collected into an approved or validated container with an anticoagulant by a trained and certified health care and medical professional. During the collection process, the following considerations must be made:
The mother and child must be protected during the UCB collection procedure. In order to raise UCB unit volume, it must be ensured that there will be no negative effects on obstetric practise or mother and infant care.
When a consenting mother gives birth in a hospital, nursing home, or birth centre under the watchful eye of the certified Registered Medical Practitioner in charge of delivery, UCB must be collected.
UCB must be collected sterilely in a disposable Polyvinyl Chloride (PVC) bag from authorized suppliers that contains sufficient sterile pyrogen. Effectively sealed with a free anticoagulant like CPD or CPD-A (citrate-phosphate-dextrose/citrate-phosphate-dextrose-adenine).
UCB collection can take done either after delivery of the child but before the delivery of placenta or else after the delivery of placenta. The facility must take extra precautions for in utero UCB collection to ensure the safety of both the mother and the baby donor.
Only simple delivery should be used for UCB collecting .If there are several gestation, the infants should be delivered before the UCB is collected. Before UCB collection, the supervising RMP shall guarantee the infant's safety if the newborn is delivered at a gestational age less than 34 weeks.

STATUTORY PROVISIONS
In recent era the need for umbilical cord blood stem cell has urged as its curing property for various malignant and non- malignant diseases have been found. So it replaced bone marrow for treatment of various diseases as umbilical cord blood stem cell is more advantageous than bone marrow. As this demand raised across the globe the need for regulating the use of such stem cell and collection of these stem cells has become an important subject, thus various regulations were adopted by different countries around the world

GUIDELINES BY WORLD HEALTH ORGANISATION

The World Health Organization issued guidelines regarding collection and storage of cord blood which aims to ensure the quality and safety of cord blood for clinical use. For collection of cord blood it should be done in closed system in-order to avoid contamination. And before collection of cord blood informed consent from mother. Standardized rules should be followed while processing to make sure consistency and quality. The WHO prefer using liquid nitrogen for storage of cord blood for future use , for this proper equipment and procedures to be adopted to confirm the safety and security of cord blood and also to retain its viability and performance. It also suggest for application of quality control program to make sure the safety and effectiveness of cord blood for clinical use which should include adequate testing for infectious agents, also to check the performance and cell viability. Ethical side were specified by WHO in collection and storage of cord blood. And also must ensure the privacy and confidentiality of the donor and recipient are protected.

OVERVIEW OF REGULATIONS IN EUROPEAN UNION

After the success story of cord blood transplant treatment for Fanconi's anaemia, cord blood stem cell gained its value in the medical field and which was used by related as well as non-related one for the treatment of various malignant and non- malignant diseases. In the United Kingdom other than public and private cord blood bank an innovation were introduced by mixing public and private storage it was launched by Richard Branson as Virgin Health Bank where 20% of the cord blood is stored as private owned that means for the child or any family member and 80% is donated for the public which can be accessed by anyone in the world who is in need off at free of cost .

Since cord blood banking is an important subject European Union Directives furnished union wide framework of regulations. Most European nations now have national bioethics committees, and one of these committees includes five of these nations as well as the appropriate European Union institutions, such as the European Group on Ethics in Science and New Technologies (EGE), the European Commission's Bureau of European Policy Advisers (BEPA), and the Committee of Ministers and Steering Committee on Bioethics at the European Council level.. 9 members out of 27 European Union members of the national ethics committees have published opinion regarding cord blood banking which conveyed at European Union level out of all the opinions only the most relevant scientific and clinical information as a foundation for any ethical analysis was considered.

By march 16th 2004 European Group on Ethics have published a document as " Ethical Aspects of Umbilical Cord Blood Banking. " After this the opinion from European National Bioethics Committee on cord blood banking is the summarised form of principles put by the European Group Ethics. As per the opinion of the committee " when cord blood banks were established, it has to be altruistic and voluntary cord blood donation and used for allogeneic transplantation and concerned study. Member states should not encourage cord blood donations for autologous use or the promotion of cord blood banks for such purposes. Instead, they should properly inform the public about the benefits and drawbacks of cord blood banks, and if autologous cord blood banks were established, families would need to be informed before their consent could be obtained for cord blood storage.

US REGULATIONS ON CORD BLOOD BANK

Laws were adopted by 31 states of Unite States. These laws directed towards educating expecting parents about cord blood banking. In accordance with this the Institute of Medicine provided congress with a report which specifies the use and benefits of stem cells found in umbilical cord blood. This report points for establishing a National Stem Cell Bank Program which is meant for collecting, distributing and use of cord blood.

In the United States the collection, processing and storage of cord blood are regulated by the Food and Drug Administration. Only healthcare professionals are licensed to collect the cord blood and must be done with the sterile , closed system to prevent contamination. These collected cord blood are processes as per the regulations prescribed by the Food and Drug Authority to keep up its safety and efficiency which must be carried out in a licensed place and ha to be stored as per the criteria made by Food and Drug Administration, and also the details of both the donor and recipient must be kept private. Other than regulations by Food and Drug Authority National Marrow Donor Program also put forth regulations regarding collection and storage of umbilical cord blood.

AUSTRALIAN REGULATIONS ON CORD BLOOD BANK

The Therapeutic Goods Administration (TGA), which is the country's regulating body for therapeutic goods, including blood and blood products, regulates the collection, processing, and storage of cord blood in Australia. The following are some important laws governing cord blood banking in Australia:

Only healthcare personnel who have been approved by the TGA may take cord blood samples. To avoid contamination, the collection must be done in a closed system.

To ensure the safety and effectiveness of cord blood, processing must be done in accordance with Therapeutic Goods Administration regulations. A licensed facility that complies with Therapeutic Goods Administration guidelines for the handling and storage of biological materials must carry out the processing. Cord blood must be kept in a facility with a licence and that complies with Therapeutic Goods Administration guidelines for handling and storage of biological materials must carry out the processing. Cord blood must be kept in a facility with a licence and that complies with Therapeutic Goods Administration guidelines for handling.and preservation of biological substances. The facility's processes and equipment must be suitable for ensuring the security and safety of the cord blood. To guarantee the safety and effectiveness of cord blood for therapeutic use, cord blood banks must put in place a quality control programme. This programme must monitor cell viability and functionality as well as conduct routine tests for infectious agents. Before collecting cord blood, cord blood banks must get the parents' informed consent. The parents must give their informed consent after being fully informed of the benefits and drawbacks of cord blood banking. Additionally, the donor's and the recipient's secrecy and privacy must be maintained.

These rules are not the only ones; the National Health and Medical and preservation of biological substances. The National Health and Medical Research Council (NHMRC) offers standards for the moral conduct of research involving human beings, including cord blood research. The facility must contain the necessary equipment. The recommendations cover topics such as informed consent, privacy, and the defence of human subjects. Overall, Australian laws and policies are designed to ensure that cord blood is used ethically, safely, and for therapeutic and research objectives. For the safe and efficient use of cord blood, cord blood banks and healthcare professionals must adhere to certain laws and rules.

JAPAN RECOMMENDATION ON CORD BLOOD BANK

The Ministry of Health, Labour and Welfare (MHLW), which establishes standards for the collecting, processing, and storage of cord blood, oversees cord blood banking in Japan. The following are some important rules for cord blood banking in Japan:

Only medical personnel who have received permission from the Ministry of Health, Labour and Welfare may take cord blood samples. To avoid contamination, the collection must be carried out in a sterile, closed system.To ensure the safety and effectiveness of cord blood, processing must follow Ministry of Health, Labour and Welfare guidelines. A licensed facility that complies with Ministry of Health, Labour and Welfare standards for the handling and storage of biological materials must carry out the processing. Cord blood must be kept in a facility that is authorized and complies with Ministry of Health, Labour and Welfare guidelines for handling and keeping cord blood. of biological components. The facility's processes and equipment the safety and effectiveness of cord blood for therapeutic use, cord blood banks must put in place a quality control programme. This programme must monitor cell viability and functionality as well as conduct routine tests for infectious agents. Before collecting cord blood, cord blood banks must get the parents' informed consent. The parents must give their informed consent after being fully informed of the benefits and drawbacks of cord blood banking. Additionally, the donor's and the recipient's secrecy and privacy must be maintained. Additionally to these recommendations, the Japanese Society of Hematopoietic Cell Trasnplantation gives instructions on how to use cord blood for transplants in a clinical setting. The guidelines cover topics such as quality control, sample processing, and donor selection. Overall, the goals of the Japanese regulations are to guarantee the ethical, clinical, and qualitative usage of cord blood. These rules must be followed by cord blood banks and medical professionals in order to guarantee the safe and efficient use of cord blood

ARAB COUNTRIES PROVISIONS ON CORD BLOOD BANK

In most Arab countries, cord blood banking is regulated by the national health authorities. These regulations vary from country to country, and they often aim to ensure the safety, quality, and ethical use of cord blood cells for medical purposes. Some Arab countries have established national cord blood banks or public registries to facilitate the collection, storage, and sharing of cord blood cells. These banks are often part of a larger national strategy to promote stem cell therapies and research.

In some Arab countries, private cord blood banks operate under specific regulations that govern their practices and services. These regulations may cover issues related to informed consent, testing, processing, storage, and ownership of cord blood cells. Private cord blood banks are often subject to inspection and accreditation by national or international bodies.In general, Arab countries tend to adhere to international standards and guidelines for cord blood banking, such as those issued by the World Health Organization (WHO), the International Society for Stem Cell Research (ISSCR), and the American Association of Blood Banks (AABB). However, there may be some variations and adaptations to these standards based on local cultural and legal norms.

NATIONAL PROVISIONS ON CORD BLOOD BANK

The Indian Council of Medical Research (ICMR), which establishes standards for the collecting, processing, and storage of cord blood, oversees cord blood banking in India. The following are some crucial recommendations for cord blood banking in India: Only healthcare workers who have received training from and are approved by the Indian Council of Medical Research are permitted to collect cord blood. To avoid contamination, the collection must be carried out in a sterile, closed system. For cord blood to be safe and effective, it must be processed in accordance with Indian Council of Medical Research guidelines. A licensed facility that complies with Indian Council of Medical Research guidelines for the handling and storage of biological materials must carry out the processing. A licensed facility that complies with Indian Council of Medical Research guidelines for the handling and storage of biological materials is required to keep cord blood. materials. The facility's processes and equipment must be suitable for ensuring the security and safety of the cord blood. To guarantee the safety and effectiveness of cord blood for therapeutic use, cord blood banks must put in place a quality control programme. This programme must monitor cell viability and functionality as well as conduct routine tests for infectious agents. Before collecting cord blood, cord blood banks must get the parents' informed consent. The parents must give their informed consent after being fully informed of the benefits and drawbacks of cord blood banking. Additionally, the donor's and the recipient's secrecy and privacy must be maintained. The National Accreditation Board for Testing and Calibration Laboratories has additional requirements in addition to existing ones. Cord blood banks that meet (NABL's standards for quality management and technical proficiency) are accredited. Overall, the goals of the Indian regulations are to guarantee the ethical, clinical, and qualitative usage of cord blood. These rules must be followed by cord blood banks and medical professionals in order to ensure the safe and efficient use of cord blood.

GUIDELINES BY INDIAN COUNCIL OF MEDICAL RESEARCH

This guidelines was created primarily to provide information on the scientific underpinnings of umbilical cord blood storage, the current state of its therapeutic usage, and recommendations for different relate

d difficulties. It also elaborates on the ethical and scientific issues surrounding the storage of umbilical cord blood. It was created after extensive deliberation on the topic and collaboration with stakeholders, professionals, and other relevant parties for scientific proof. The text was modified from the Drugs & Cosmetic Act 1940 and Rules 1945 (Amendments 2016) and was influenced by a number of international legal texts that are in the public domain, including the Association for the Advancement of Blood and Biotherapies Standards for Cellular Therapies and the NetCord FACT Standards. It reflects what researchers and medical professionals are now thinking about the evidence that is currently available, and it will be updated when new data become available.

It might be said that the purpose of these guidelines is to support rather than replace the current regulatory standards for umbilical cord blood banking as set forth in the Drugs & Cosmetic Act 1940 and Rules 1945 (Amendments 2016).

GOAL OF THE REGULATION

The National Guidelines for Umbilical Cord Banking's major goal is to establish extra standards to address the quality and ethical aspects of UCB collection, processing, banking, and release. They also serve as a reference for all stakeholders. It aims to direct ethical, patient-centered practise that is informed by the available evidence. According to new findings in the field of study and scientific advancements, the paper will be periodically updated. These principles should not be interpreted as replacing or superseding the current regulatory obligations, but rather as supporting them.

All parties involved, including UCB banks and staff participating in all procedures, obstetricians, neonatologists, and transplant doctors, together with parents and anyone else offering support services, must abide by the rules.

COMPARATIVE ANALYSIS

Umbilical cord blood banking is an essential aspect of healthcare, where family members preserve the blood from the umbilical cord of a newborn baby to use it later for potential disease treatment.

Umbilical cord blood banks have become increasingly popular over the years as they offer potential benefits for both families and the medical community. These banks store the umbilical cord blood , that can be used for curing a variety of diseases and conditions.

A literature review on umbilical cord blood banks reveals that these banks have become a major source of stem cells for medical research and treatments. The stem cells stored in these banks are used to treat various diseases such as leukemia, lymphoma, and other genetic disorders.

One of the major benefits of umbilical cord blood banks is that they are non-invasive and pose no risk to the mother or baby during the collection process. Also, stem cells found in umbilical cord blood are less likely to be rejected by the recipient's immune system, reducing the likelihood of complications during transplantation.

However, there are concerns about the cost of storing cord blood in private banks, which can be quite expensive. Additionally, the chances of actually using the cord blood for treatment purposes are relatively low. Furthermore, there is a lack of diversity in stem cell samples stored in private banks, which could limit their effectiveness.

There are a number of parallels and divergences between Indian law and international law that should be taken into account while discussing cord blood banking. Here are a few crucial comparisons:

Informed Consent: Before cord blood sampling, parents must provide their informed consent in accordance with both Indian law and international standards. On the other hand, there can be variations in the precise specifications for getting informed consent, such as the volume of information that must be presented and the method for doing so.

Ownership of Cord Blood: In India and many other nations, the topic of cord blood ownership is a legal one. However, different nations may have different ownership laws and restrictions.

Standards and Regulations: To maintain the security of cord blood banking services, both Indian laws and international recommendations are intended to govern these services and efficiency, too. However, there might be variations in the particular laws and rules that are in force, such as the specifications for accreditation and licensing or the kinds of testing and processing that must be done.

Equity and Access: Access to cord blood banking services is a problem in India as well as many other nations. However, there may be regional variations in the specific causes of these problems, such as in the healthcare and insurance systems.

The constitutional elements of cord blood banking are important in the Indian context even though international law does not specifically address them. However, international law acknowledges the significance of safeguarding core human rights, such as the right to health, privacy, and property.

In general, while While there may be some variations in the specific laws and rules allowing cord blood banking between India and other nations, there are numerous parallels among the pertinent problems and worries. The worldwide norms and recommendations on cord blood banking offer a beneficial framework for nations to take into account when creating their own laws and rules.

A crucial component of healthcare is umbilical cord blood banking, in which parents store a newborn baby's umbilical cord blood in order to use it for potential medical treatment in the future.Umbilical cord blood banking is still a relatively new practise in India, and it is still in its

infancy. Only 5% of the cord blood produced in the nation is thought to be kept in public or private cord blood banks.
On the other side, nations with a strong network of public and private cord blood banks include the US, Canada, and Australia. Governments in these nations have established policies, rules, and procedures for securely collecting, moving, and storing cord blood.
Additionally, nations like Singapore, Korea, and Japan have established to prevent patients from needing to pay for expensive stem cells from international banks.

The collection, processing, and storage of cord blood stem cells are not subject to any federal regulations in the US. To guarantee that the procedure is secure and efficient, the Food and Drug Administration (FDA) has developed criteria for cord blood banking facilities. Companies must abide by the laws and rules that apply in each state.

Regulations from both the federal and provincial governments in Canada apply to cord blood banking. The cord blood banking process is governed by Canadian law, which also mandates that the institution have a Health Canada licence. In accordance with Canadian law, families must also be given thorough information regarding the potential advantages and drawbacks of cord blood banking.

The Human Tissue Authority in the United Kingdom oversees cord blood banking, and cord The authority must issue licenses to blood banks. Additionally, they are subject to rigid safety and quality regulations.

The Australian government similarly controls cord blood banking. The Australian government encourages both public and private cord blood banking, and the Australian Therapeutic Goods Administration licence is a requirement for cord blood banks.

In conclusion, even though there could be some variations in the particular rules and laws pertaining to cord blood banking in different nations, the most of them have policies in place to guarantee the security and effectiveness of the procedure.But compared to other industrialized nations, the practise of banking umbilical cord blood is relatively recent in India. But as people become more aware of the advantages of stem cells and cord blood banking, more and more individuals are probably going to choose it in the future.

LEGAL ISSUES

Lack of proper law or legislation will lead to vagueness or ambiguity regarding any matter. In recent year almost by the mid twentieth century umbilical cord blood collection has attained popularity as it is a source of stem cell and thus the need for umbilical cord blood bank as also raised as the societal need as increased, but there was a major problem that was faced by every nation which was lack of proper law for the regulation of this process. Even if there are many regulations regarding this topic were framed by many countries but still there is lack of codified law related to this matter which had raised many legal issues main among which is protection of the details of both the donor and recipient, other is whether the cord blood should be donated to public cord blood bank so that the general public who is in need can access to it or to be donated to the private bank which is expensive and can only get accessed by the donor or any of his or her family member. Other issue which is to be considered that while giving cord blood to any needy person by the public cord bank then whether it is to be informed to the donor or not and there are many such issues which also has ethical issues too. The ownership of cord blood is a contentious issue that has been debated for years. In most cases, parents have the right to decide whether or not to donate cord blood for public or private use. However, some countries, such as France and Italy, regulate the donation of cord blood and only allow it to be used for public purposes. Informed consent is required for the collection, storage, and use of cord blood. This implies that parents must be fully informed of the risks and benefits of cord blood banking before making a decision. Therefore, some countries, such as Spain, require written consent before cord blood can be collected.

Privacy laws dictate who has access to cord blood and how it is used. For instance, in the United States, the Health Insurance Portability and Accountability Act (HIPAA) keep up the secrecy of medical information, including cord blood information. Cord blood banks offered by private companies are not regulated in most countries, making it hard to predict quality standards. This lack

of regulation can lead to the exploitation of vulnerable and uninformed parents. Hence, several countries, such as Canada, have regulations in place to govern the cord blood banking industry.
Access to cord blood is another issue that has garnered attention worldwide. Many countries allow parents to donate cord blood to public banks, which can then be used for research or medical treatments. However, some countries, such as the United Arab Emirates, prohibit the export of cord blood, and therefore limit access to stem cells.
the legal issues surrounding umbilical cord blood collection vary by country. However, they all reflect the importance of informed consent, privacy, and regulation to ensure that cord blood is collected ethically and used appropriately.

LEGAL ISSUES IN INDIA

Numerous legal concerns surrounding cord blood banking have generated discussion and debate in India. The following are some of the major legal concerns with cord blood banking in India:
The legal prerequisite for cord blood banking in India is informed consent. Before cord blood is collected, parents must be fully informed of the benefits and hazards of cord blood banking and must provide their voluntary consent. Concerns have been raised about the quality of the information given to parents and their comprehension of the advantages and disadvantages of cord blood banking. In India, there is no definite legal structure for establishing cord blood ownership. Some some contend that cord blood belongs to the child while others assert that it does. The ownership and usage of cord blood may be a source of contention after divorce or separation, which can make this situation extremely complicated.
There have been issues with the absence of consistent standards and rules for cord blood banking in India. Although the Indian Council of Medical Research offers recommendations for cord blood banking, no regulatory organization is in charge of monitoring their application. This has raised questions regarding the effectiveness and safety of India's cord blood banking systems. Cord blood banking is a costly service that is primarily accessible to those who can afford it. This raises questions regarding access to healthcare and equity. To ensure that these services are accessible to a wider number of people, there have been requests for the government to increase support and financing for cord blood banking services.
The need for more uniformity and clarity in the legislation and practise of cord blood banking in India is often highlighted by these legal challenges. In an effort to solve these problems, national regulations are being created, and organizations to regulate the cord blood banking industry are being established. One of the main issue is that lack of public cord blood bank because of which the cord blood is donated to private cord blood bank which restrict the access of general public which can also be taken to the aspect of violation of fundamental right of a person to get proper medical treatment.
Preserving cord blood in private cord blood bank will lead to wastage of cord blood as the chance for having these diseases is only probability and not a sure matter. If there is any history of leukemia or such disease then the chance may be high but if there is no such family history then it is of less probability, thus keeping umbilical cord blood in the private cord blood bank will lead to wastage of money as well as the potent stem cell if no one in that family need its use which inter is preventing any needy person from accessing to his means of treatment which will save his life.

CONSTITUTIONAL PROVISIONS AND CORD BLOOD BANKING

The constitutional implications of cord blood banking in India are significant in terms of the corresponding legal concerns. Main provision which deal with this aspect is Article 21 which is not only available to the citizens but also to the non- citizens too. The following are some significant constitutional considerations pertaining to cord blood banking in India:
Right to Health: According to the Indian Constitution, everyone has a basic right to good health. This includes the right to health information and the ability to use healthcare services. When parents have access to accurate and thorough information regarding cord blood banking, they may make educated decisions about their own and their child's health. Cord blood banking can be considered as a healthcare service.
Right to Privacy: The Indian Constitution declares that everyone has a basic right to privacy. This encompasses the ability to control over one's own biological and genetic makeup. This means that in the case of cord blood banking, it is up to the parents to determine whether to keep and how to use

their child's cord blood.Right to Property: According to the Indian Constitution, everyone has the fundamental right to their own property. This covers the ability to possess and manage one's own property. This implies that parents may be able to claim ownership of their child's cord blood in the context of cord blood banking.Directive Principles of State Policy: The Indian Constitution contains Directive Principles of State Policy, which serve as a road-map for the government in creating and carrying out legislation and regulations. Among these concepts is the state's duty to providing healthcare services and to advance people's well-being. It is possible to think of cord blood banking as a medical service that advances public welfare.

Overall, these constitutional considerations emphasis how crucial it is to safeguard people's rights when it comes to cord blood banking. The availability of complete and accurate information, the rights to one's property and privacy, and the government's duty to advance healthcare and welfare are all pertinent to the moral and legal questions surrounding cord blood banking in India

LEGAL AND ETHICAL ISSUE

Legal ramifications of requests from parents to obtain cord blood after the delivery .When the foetus entirely exits the mother's body, that is when it legally transforms into a person.The mother has the absolute right to consent to any changes made to her body up until that point, and the doctor is required to respect her autonomy. When a child is fully developed, the parents' right to decide what should be done for them coincides with what is in their best interests. Unless it is in the kid's best interests, the parents cannot insist that anything be done to the child that would put the youngster in danger. This holds true for both the birth attendants and the child doctor. Legally speaking, the placenta belongs to the mother's body rather than the child's.

Any action that is taken on behalf of the baby may be approved by either parent, but only the mother may provide her approval, even for the collection of cord blood.

In addition, the medical personnel assisting the expectant mother have a professional obligation to accommodate her reasonable requests. Therefore, if she requests that cord blood be taken and the medical practitioner is when the attendants are confident that it can be done safely given the conditions, they should help. The mother cannot insist that staff be made available particularly for the purpose or that other patients be put at risk by being left unattended; the phrase "safely in the circumstances" must be read widely. Hospitals that offer obstetric services would be wise to have a clear policy on this matter and to make it available to patients. We advise hospitals to clearly communicate to potential parents that this agreement will be subject to the clinical and logistical demands on the service locally at the time where they feel they will be able to safely deliver this service to those who seek it.

OWNERSHIP ISSUE

The question of who owns cord blood has not yet been litigated in a court of law. On the one hand, it has been argued that the cord blood sample is more likely to belong to the child because it is a part of their development, biology, and genetic make-up. On the other hand, it could be argued that it is more likely that the sample will become the mother's property once the cord is cut. For instance, the mother has the unrestricted right to consent to any procedure performed on her own body, so once the cord is cut, she is free to refuse to consent to the removal of the afterbirth. Usually, genetic identification is not the basis of legal property rights. the cable depending on the terms of the consignment, blood that has been entrusted to storage may be the topic of a gift from the mother to her kid. If accurate, this raises additional questions about how to use the products made from the sample that was obtained.

If it is determined that the item is being kept for the child's use, it will be held in trust for the child until the child reaches adulthood and the trustee, who is likely to be the mother, may exercise the right to use the item in the child's best interests, subject to the court's decision in the event of a disagreement. Directed donation for a sibling could be seen as optimal for the family's needs and,hence, of the foetus from which it was extracted. Any trust will expire after the child turns 18 and the person identified in the consignment contract as the beneficial owner will determine how to use the cord blood that has been stored.

Having cord blood donated to a bank poses many problems. Here, the mother makes the choice to give a product for use by others, and as the cord blood is extracted from the maternal side of the

clamp, it does not become a part of the independent child's body. The mother decides to donate it to the community because she believes that doing so will benefit both the mother and the society as a whole.members who have a child.

Since the newborn is the source of the blood, privacy is especially important. It is generally acknowledged that it would be wrong to undertake any genetic testing on the blood until the child is 18 years old or has the mental capacity to make such decisions. Although it hasn't been proven whether a child of legal age has any rights over the cord blood and stem cells their parent has stored in a bank, it seems likely that they will be considered to have been the recipient of a gift from the mother to the bank at the time of harvesting.

In conclusion even though there are regulations which deals with various process of umbilical cord blood collection both nationally as well as internationally but still there exist lacunae in those regulations it need reformation as the societal needs as changed and the umbilical cord blood banking in these days are more popular thus ambiguity regarding various issues like obtaining consent, storage of blood, ownership of the blood donated etc should be addressed in very clear manner

CONCLUSION

Umbilical cord which was a medical waste earlier is now a medically valuable thing which is used for curing many malignant and non-malignant diseases and also the researchers are conducting more research upon umbilical cord blood to find more curing property of the same. During the study it was understood that umbilical cord blood banking as emerged as a significant unit across the globe many countries have made their guidelines and regulations to govern the functioning and establishment of the cord blood bank. In the international scenario European union has made regulations for this purpose for this they have formed committees of each member state and European Group Ethics committee and they have put forth their recommendations and guidelines regarding this issue. Other than Europe US, China, Japan, Spain etc have also made regulations for this area. But still there are ambiguity with the matters related with this as there is no proper codified law and those regulations which already exist also contain lacuna with in it as certain issues like ownership of the blood collected , regarding the awareness among the public related to donation of this cord blood how it will be used for the treatment purpose , donating to public cord bank or to private cord bank which is the better option, there is also no proper idea regarding the criteria that is to be followed while transferring cord blood among different countries. More over there is no prescribed fee structure for storage of cord blood in private banks in accordance with the private cord blood bank unit may set their fee which they charge from the donor, so that these donors is not exploited by the private cord blood bankers. Therefore the need for proper codified law both for each nation and also internationally is important .

SUGGESTIONS

- Enactment of separate law for cord blood bank is essential :
  - to check the whether parents are informed before hand about the cord blood donation.
  - to get an idea about what all information should be provided to the donor before obtaining consent of donation.
  - to regulate the fee that should be charged from public by the private cord blood bank.
  - to regulate transfer of cord blood between different countries.
  - to give clarity regarding ownership the cord blood stored that is whether the parents or the bankers or the child itself after he or she attain the age of majority
  - to remove ambiguity about the whether consent from the donor should be obtained before the giving cord blood to any one who is in need from public cord blood bank
  - to specify about the protection of confidentiality of the details of both donor and recipient
- Proper awareness program should be conducted to make public understand about the pros and cons of cord blood donation how the treatment using this will be conducted, who can use the cord blood, where should they donate the cord blood and also the need for promoting public cord blood

- Public cord blood bank should be promoted more as it create an hope in the mind of needy ones as they too can access the cord blood for treatment..
- Some medical professions said that umbilical cord blood which was collected from the donor cannot be used for treatment of genetic disease of the same person because the stored contain the same genetics variant cell which will create the same condition which is been treating. Thus donation to public cord blood bank to private cord blood bank is better option.
- Strict provisions should be made so that the banking unit will keep up all the standards that to be followed and also will adhere to the safe procedure while dealing with storage so that the viability of cell is not affected.

REFERENCE

1. Gluckman E, Broxmeyer HA, Auerbach AD, et al. Hematopoietic reconstitution in a patient with Fanconi's anemia by means of umbilical cord blood from an HLA- identical sibling. N Engl J Med. 1989; 321:1174-8
2. Smith AR, Wagner JE. Alternative haematopoietic stem cell sources for transplantation : place of umbilical cord blood. Br J Haematol. 2009 ; 147: 246-61.
3. Wall DA. Best Pract Res Clin Haematol. 2010. Regulatory issues in cord blood banking and transplantation
4. The Editors of Encyclopaedia Britannica- Umbilical cord embryology
5. Joanne Kurtzberg, MD- UPDATE ON UMBILICAL CORD BLOOD TRANSPLANTATION
6. The American College of Obstetricians and Gynecologists- Umbilical Cord Blood Banking
7. Indian Council of Medical Research - Guidelines Umbilical Cord Blood banking
8. Herlihy NM, Delpapa EH- Obstetricians and their role in cord blood banking : promoting a public model, Journal of Obstetrics and Gynecoogy. 2013 Apr; 121(4):851-5
9. .Annas GJ. Waste and longing . The legal status of Plancental - blood banking. New Engl J Med. 1999;340:1521-4 .
10. Editorial Umbilical Cord blood banking Richard Branson's Way. Lancet. 2007;369:437
11. EuropeanGrouponEthicsinScienceandNewTechnologies.Opinion19.Ethicalaspectsofumbilicalcordbloodbanking.16March2004.http://ec.europa.eu/bepa/european-groupethics/docs/avis19_en.pdf
12. Parent's guide to cord blood foundation- US states regulation on cord blood
13. Monica M Matsumoto, Rana Dajani, Kristin R W Matthews - *BIOLOGY OF BLOOD AND MARROW TRANSPLANTATION*-Cord Bood Banking in the Arab World.
14. National Library of Medicine-ModelCriteria for Regulation of Cord Blood Banks and Cord Blood Association, Board of Directors, January 29, 2019
15. Indian Council of Medical Research - Guidelines Umbilical Cord Blood banking
16. Joanne Kurtzberg, MD, UPDATE ON UMBILICAL CORD BLOOD TRANSPLANTATION
17. Munoz J, Shah N, Rezvani K, Hosing C, Bollard CM, Oran B, et al Concise review: umbilical cord ion blood transplantation : past, present, and future. Stem cell transl med 2014 ;3:1435-45
18. Munoz J, Shah N, Rezvani K, Hosing C, Bollard CM, Oran B, et al Concise review: umbilical cord ion blood transplantation : past, present, and future. Stem cell transl med 2014 ;3:1435-45
19. Joanne Kurtzberg, MD, UPDATE ON UMBILICAL CORD BLOOD TRANSPLANTATION
20. Jennifer D Newcomb, Paul R Sanber et al. Umbilical Cord Blood Research : Current and Future Perspectives. 2007; 16(2): 151-158
21. O Hassall, L Ngina and I Bates, The acceptability to women in Mombasa Kenya, of the donation and transfusion of umbilical cord blood for severe anemia in young children.
22. Suen SS Lao TT et al, Maternal understanding of commercial cord blood storage for their offspring- a survey among pregnant women in Hong Kong Australian Journal of Obstetrics and Gynecology. 2011 sep; 90(9): 1005-9
23. Caslistri D, Cofano R,: A great lack of knowledge regarding umbilical cord blood banking among pregnant women in Berlin, Germany, Journal of perinatal Medicine. 2011 Mar;39(2);217
24. Indian Council of Medical Research - Guidelines Umbilical Cord Blood banking
25. Jennifer D Newcomb, Paul R Sanber et al. Umbilical Cord Blood Research : Current and Future Perspectives. 2007; 16(2): 151-158
26. Dr JN Pandey - Constitutional law

