CORD BLOOD BANKS: TYPES AND ACCREDITATIONS: A REVIEW

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ABSTRACT
Background: Cord blood banking has evolved in types, characteristics and international acceptability since the world's first cord blood banks was established in 1991. The trend of the developments exists in different literature spread all over of the world.
Aim: A review of the types and characteristics of umbilical cord banks (UCB) was done to chronicle the developments from the establishment of the first UCB to present. The introduction of accreditations for international acceptance was also reviewed to highlight the importance of the accreditations and the globally accepted accreditation bodies. This review brings together information from the various sources into an easily accessible document.
Methodology: The sole instrument for this work was the critical review of all available academic, professional and industry documents on cord blood banking. The relevant information was obtained from textbooks, academic journals, conference proceedings, the internet among others.
Results: The review revealed that today, there are more than 500 active cord blood banking facilities made up of 352 private cord blood banks and 174 public cord blood banks spread out across more than 100 different countries. There are two major types of UCBs: private and public UCBs. Private cord blood banks are usually for-profit enterprises that offer UCB storage exclusively for the child or family members. A significant advantage of a private cord blood bank is the exclusive accessibility and the immediate availability of the cord blood, should the need arise. Public cord blood banks store unrelated cord blood units that are philanthropically donated for allogeneic transplantation or research purposes. Public UCBs are funded by philanthropic grants and donations, the sale of the cord blood units and supported by the government or foundations. Nearly 90% of public cord blood banks by 2014 have declared that they are struggling to maintain their financial sustainability and avoid bankruptcy. A newer type of CB bank is the hybrid model, which offers a combination of public and private CB storage. Different models of hybrid banking exist around the world. Direct-donation umbilical cord blood banks function as an amalgamation of public and private banks. This type of banking is solely for sibling donor collection for those families who are likely to consider CB transplantation because a pedigree relative has been diagnosed with a disease that is treatable with allogeneic CB transplantation. Internationally accepted and recognized accreditations are important for a cord blood bank. Accreditations certify that the blood bank has been appraised by authorized bodies for competency, credibility, operational efficiency, and quality management of processing and cryopreservation protocols to ensure the safety of the umbilical cord blood stem cells that are being preserved. The standards for CB banking must be international, since CB products frequently cross international borders. NetCord-FACT International Standards for cord blood collection, processing, testing, banking, selection and release are set to promote quality practices and to consistently assure the provision of quality cord blood units for transplantation. Today AABB is the world leading UCB accrediting body. While optional, AABB accreditation is considered one of the most important global credentials that a cord blood bank can hold.
Conclusion: The number of umbilical cord blood banks have grown over the recent decades. There are currently more private umbilical cord blood banks than there are public umbilical cord blood banks as the existing public UCBs are facing the issue of funding. Hybrid UCBs and Direct-donation UCBs are more recent forms of UCB. All UCBs now require accreditations for international acceptability.
Keywords*:* Umbilical Cord blood banks, public cord blood banks, private cord blood banks, hybrid

INTRODUCTION

The motivation to store cord blood varies from person to person. For some, there might be an immediate need within the family to treat a disease amenable to transplantation, for example to a sibling or a closely matched family member. Alternatively, a woman or a couple might donate altruistically (as with blood donation) by offering the cord blood as a public resource to be available for others with the need for an immediate transplant. Finally, some donors choose to contribute to research. Umbilical cord blood (UCB) gifted to non-profit public cord blood banks is now routinely used as an alternative source of haematopoietic stem cells for allogeneic transplantation for children and adults with cancer, bone marrow failure syndromes, haemoglobinopathies and many genetic metabolic disorders. The increasing demand for UCB led to the establishment of cord blood banks, where the blood is cryopreserved and stored for future recipients (Laue *et al*., 2023). There are four different types of umbilical cord blood: public cord blood, private cord blood and hybrid cord blood banks. There is also a direct donation cord blood bank (Chan, 2006).

Types of Cord Blood Banks

Public Cord Blood Banks

Public cord blood banks store unrelated cord blood units that are philanthropically donated for allogeneic transplantation or research purposes. Costs of collection and storage are covered by philanthropic grants and donations, financed through the sale of the cord blood units and supported by the government or foundations (Armitage, 2016, Guilcher *et al*., 2015). Without national support, public CB donation will never be an option for every potential donor (Armitage, 2016).

Nearly 90% of public cord blood banks by 2014 have declared that they are struggling to maintain their financial sustainability and avoid bankruptcy (Magalon *et al*. 2015). A survey conducted by the World Marrow Donor Association (WMDA) revealed that only 16 of 139 public cord blood banks operating worldwide in 2013 were financially sustainable (WMDA Annual Report Cord Blood Bank/Registries, 2013). The number of cord blood units (CBUs) transplanted in Europe has dwindled steadily from 2010 to 2019 (Foeken and Orsini, 2015). This decline has been attributed to the emergence of haploidentical transplantation which represents an alternative to cord blood transplantation (El-Cheikh, *et al.*, 2015). Katz, (2015) reported that in 2014, France decided to shut down half of its operating public banks just two years after launching a national development plan to support public banking. Public banks are so economically vulnerable that only the best should be eligible for cryopreservation (Eapen *et al*., 2007)

Umbilical cord blood units stored in public banks must meet specific quality criteria, such as a minimum nucleated cell count and volume. In addition to that, collected cord blood needs to be free from microbial contamination and the infant's birth data must be documented to rule out any communicable diseases (Laue *et al*., 2023). The relevant information (e.g. human leucocyte antigen (HLA) types, cell counts, and some cases, the donor's medical history) is stored in a database made available to transplant centers searching for a cord blood unit for patients (Cord Blood Bank Standards; Available on http://www.factwebsite.org/cbstandards/). This registry can be searched internationally and if a match is found, the cord blood unit will be discharged in exchange of a release fee (Chang, 2016). Greater chances of finding a suitable match for the patiens'blood coupled with the risk of non-usability of the blood unit stored in private bank are some of the prime factors anticipated to boost the growth of the public banks shortly.

The chance of a sibling being a full HLA match is 25%, and given the small size of modern families, there is a significant proportion of patients (40–50%) for whom neither a sibling donor nor an unrelated bone marrow donor can be found (Sullivan, 2008). This is one of the reasons why public cord blood banks were established.

In the absence of any published transplant evidence to support autologous and non-directed family banking, commercial cord banks currently offer a superfluous service (Sullivan, 2008).

The American Society for Blood and Marrow Transplantation's view is that donation of cord blood to public is preferable because the use of cord blood stored in private cord blood banks for therapy rarely occurs, about 1 in several 1000 (Delaney *et al*., 2013). Other professional groups that favor public cord blood bank donations over private cord blood banking include the International Federation of Gynecology and Obstetrics and the United Kingdom's Royal College of Obstetricians and Gynecologists (Cutler and Ballen, 2012). The issues of collection, storage, and use of cord blood (CB) stem cells have been addressed extensively in national and international guidelines, policies, and regulations. There is a consensus in the guidelines that public storage for allogeneic transplants is preferable and that private storage should be discouraged (Petrini, 2012).

Screnci *et al*., (2012) showed from their study that more than half of pregnant women (55%) would have chosen to donate the cord blood to a public bank for altruism and also for the existing possibility of recovering, if necessary, the donated sample if it were to be still available. Some public banks also store a limited number of units for autologous or family use when a disease that is treatable by cord blood transplantation is known to exist within the donor's family. In these circumstances, the blood is often stored for a short time and the bank provides the necessary processing and testing to aid the transplant physician (Shearer *et al*., 2017).

The world's first CB bank was established at the New York Blood Centre, United States in 1991 (Rubinstein, 1995). Other banks were soon operating in Paris, France, Milan, Italy, Germany and Düsseldorf in 1992 (Gluckman and Rocha, 2005).

Private Cord Blood Bank

Private cord blood banks store cord blood units only for autologous or family use. These banks tend to describe their service as offering "biological life insurance" that provides peace of mind to families that might be concerned about future health conditions in the child or a close relative for which cord blood transplantation might be a possible treatment. Private cord blood banks are usually for-profit enterprises that offer UCB storage exclusively for the child or family members (Hauskeller and Beltrame, 2016). These banks generally charge a fee for the collection, processing, and storage of the cord blood and leave any decisions regarding the use of the unit to the donor or the donor's family. The general charges globally involve an initial banking cost of about $1,000 to $2,000 and then a yearly maintenance fee of $50 to $150 (Howard *et al*., 2005). The average cost in Canada is about $1200 for processing and first year of cryopreservation. Subsequent yearly storage fees generally run between $100 and $130 (Armson *et al*., 2015). Alternative payment plans are often offered, including an 18-year single-cost plan in some cases. Eighteen years is a logical term for such a plan since the child from which the cord blood was collected will have reached the age of maturity at the end of the term and can then decide whether or not to continue to bank the CBU (Armson *et al*., 2015). Private banking is associated with significant costs for the family (Guilcher *et al*., 2015) and there is a risk that a bank stops trading or goes bankrupt (Fisk and Atun, 2008). Ballen *et al*. (2015) reported the results of 59 private cord blood banks surveyed for case reports of family cord blood units released for clinical use and compared these results to the World Marrow Donor Association data on public cord blood storage and release for clinical use. By the end of 2013, the inventory of private banks was about 6 times higher than that of public cord blood banks; yet public banks have released about 30 times more units for transplantation (Ballen *et al*., 2015).

Statistics from the European Society for Blood and Marrow Transplantation (EBMT) (Jakob *et al.*, 2021) show that the vast majority of UCBT in Europe was used for allogeneic indications, while only zero to six transplants per year were autologous (Figure 1).

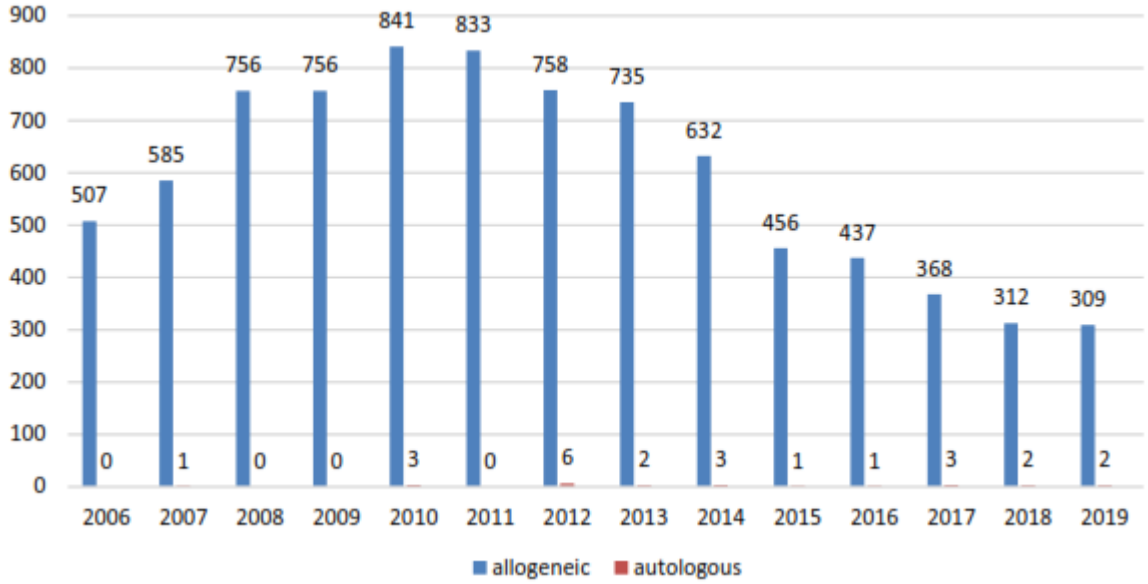

Figure 1: Allogeneic versus Autologous Cord Blood Transplants in Europe.
Source: Jakob et al., 2021

Private cord blood banking is not cost-effective, and will only become economical when banking costs less than $262 or the likelihood of a child needing a stem cell transplant is greater than 1 in 110 (Kaimal *et al*., 2009). The only significant advantage of a private cord blood bank is the exclusive accessibility and the immediate availability of the cord blood, should the need arise. Also when public banking is not available, private banking may be the only option to store UCB (Guilcher *et al*., 2015). In some countries, public UCB banks are neither funded nor promoted by the governments. Examples of such countries include Taiwan and India which have mostly established private banks because of a lack of funding or support for public UCB banks (Hauskeller and Beltrame, 2016, Patra and Sleeboom-Faulkner, 2016).

Also, if the strict inclusion criteria for public banking are not met, private banks still offer parents an opportunity to store their child's cord blood, as private banking conditions are less restrictive (Guilcher *et al*., 2015). Specifically, public banks only store UCB with a large nucleated cell number for economic reasons, as the probability of being able to release and sell it increases with a higher cell count (Laue *et al*., 2023).

Hybrid Cord Blood Banks

A newer type of CB bank is the hybrid model, which offers a combination of public and private CB storage. Interest gaps between public and private umbilical cord blood banks led to the introduction of hybrid banking options. Hybrid models combine features of private and public banks as well as the interest of parents, children and of patients, to find an optimized solution (Laue *et al*., 2023). The line between public and private cord blood banking is being increasingly blurred by the emergence of "hybrid models" that combine aspects of both the public and private systems (Michelle *et al*., 2012). Hybrid banking is actually a general term for banking practices that combine elements of public and private storage (Hauskeller and Beltrame, 2016).

Different models of hybrid banking exist around the world (Wagner *et al*., 2012). Some hybrid banks store a portion of the CB unit publicly and another portion privately, whereas others give parents the choice to either donate the CB for public storage or keep it privately. In either case, hybrid banks can use the revenue from private storage to offset the costs of the public side and can have the added advantage of providing parents with a choice (Matsumoto *et al*., 2015).

Michelle *et al*. (2012) distinguished two broad categories of hybrid UCB banks (Table 1). First, instead of offering parents either public donation or private storage, some banks are now offering both options. Secondly, other banks make privately stored cords blood available to the public system of donation. The private banks make available cord blood to the public in different models named after the place they have been perfected.

Table 1: Hybrid Models of Umbilical Cord Blood Banking

Type of hybrid	**Model**	**Description**
Cord blood banks that offer both public donation and private storage options	Private banks that offer a public donation option	Several private banks now offer to store donated cord blood for use in allogeneic transplants. eg LifeforceCryobanks in the United States. Eticur in Germany, Eurocord in Slovakia and Cryosave in Belgium (which provides the not-for-profit health foundation Osidea with storage facilities for donated cord blood).
	Private banks that offer a public donation option (Charitable Family Model)	Since 2005 the Alberta Cord Blood Bank in Canada has offered cord a private storage option to generate funding.
Innovations that make privately stored blood available to the public system	Turkish model	According to government legislation, 25% of all privately stored cord blood is donated to the public system.
	Spanish model	Cord blood stored in a private bank is recorded on the official Spanish Register of Bone Marrow Donors. Should a patient in need of a transplant find a correct human leukocyte antigen match, parents are obliged to donate the cord blood and the storage fee is reimbursed.
	Virgin model (Split model)	80% of the cord blood is donated to the public sector and 20% is stored for private use. Profits are used to fund stem cell research.
	Private banks that provide an option to release stored cord blood for public use	Several German banks offer parents the option of privately stored cord blood which can be released for use if it is matched to a patient who needs an allogeneic transplant. Parents are under no obligation to release the blood if a match is found. VITA34 bank offers this as an option called *VitaplusSpende* and Eticur offer this as an option called *Eticur: Kombi.* Both banks also offer parents the option of storing cord blood privately for autologous use only.

Source: Michelle *et al*., (2012)

Direct-Donation Bank

Direct-donation umbilical cord blood banks function as an amalgamation of public and private banks. Direct-donation banks collect cord blood without charging fees. In addition, they accept autogenous donations and reserve them only for the family, especially for a family whose infant has a sibling with a disorder that may be treated with umbilical cord blood stem cells (Moes, 2005). This type of banking is solely for sibling donor collection for those families who are likely to consider CB transplantation because a pedigree relative has been diagnosed with a disease that is treatable with allogeneic CB transplantation (Gluckman *et al*., 1997).

Cord Blood Bank Distributions in the World

In early 2000, there were only a few dozen cord blood banks worldwide. By 2012 there were about 53 public cord blood banks which stored donated cord blood for public access worldwide(Ref). These banks were listed on national and international registries and networks that can be searched by clinicians who are looking for a donor for a child or adult requiring a transplant. Bone Marrow Donors Worldwide (BMDW) had at then listed 44 cord blood banks from 26 different countries that contain 446,817 units of cord blood (Michelle *et al*., 2012). Manegold *et al*. (2011) reported that approximately 800,000 cord blood units are stored in private banks, which far exceeds the number stored by international stem cell registries for public use.

Today, there are more than 500 active cord blood banking facilities made up of 352 private cord blood banks and 174 public cord blood banks spread out across more than 100 different countries (Table 2) as listed in Parents' Guide to Cord Blood Foundation database. The United States of America tops the list with 43 cord blood banks which makes up 8% of the worlds' total. Eight countries in Africa hold 15 of the banks the equivalent of 2% of the world total (Manegold *et al*., 2011). Some of these cord blood facilities are not necessarily full cord banks but some are collection centres and processing laboratories.

The first 15 countries ranked by the number of cord blood banks are the USA, Italy, Spain, Germany, United Kingdom, India, Canada, Israel, Brazil, Australia, Belgium, Poland, Chile, Cyprus and China. Some of these cord blood banks listed are actually hybrid in operation.

Table 2: Distribution of Cord Blood Banking Facilities in the World

S/N	Country	Private	Public	Total
1.	Andorra	1	-	1
2.	Albania	2	-	2
3.	Argentina	10	1	11
4.	Australia	1	3	4
5.	Austria	2	1	3
6.	Bahrain	5	-	5
7.	Bangladesh	1	-	1
8.	Belgium	0	5	5
9.	Bolivia	1	-	1
10.	Bosnia and Herzegovina	3	-	3
11.	Brazil	11	12	23
12.	Brunei	1	-	1
13.	Bulgaria	4	-	4
14.	Cambodia	1	-	1
15.	Canada	6	3	9
16.	Chile	3	1	4

17.	China	10	8	18
18.	Colombia	5	1	6
19.	Congo (Kinshasa)	1	-	1
20.	Costa Rica	4	-	4
21.	Croatia	1	1	2
22.	Cyprus	3	1	4
23.	Czech Republic	2	1	3
24.	Denmark	2	-	2
25.	Dominican Republic	2	-	2
26.	Ecuador	4	-	4
27.	Egypt	5	-	5
28.	Estonia	2	-	2
29.	Finland	0	1	1
30.	France	00	5	5
31.	Georgia	1	-	1
32.	Germany	2	9	11
33.	Ghana	1	-	1
34.	Greece	8	3	11
35.	Guatemala	2	-	2
36.	Honduras	2	-	2
37.	Hong Kong S.A.R., China	5	2	7
38.	Hungary	4	-	4
39.	India	11	1	12
40.	Indonesia	3	-	3
41.	Iran	1	1	2
42.	Israel	3	3	6
43.	Italy	9	19	28
44.	Japan	2	6	8
45.	Jordan	2	-	2
46.	Kazakhstan	1	-	1
47.	Kenya	2	-	2
48.	Kuwait	5	-	5
49.	Latvia	5	-	5
50.	Lebanon	6	1	7
51.	Lithuania	2	-	2
52.	Luxembourg	1	-	1
53.	Macao S.A.R., China	3	-	3
54.	Macedonia	2	-	2
55.	Malaysia	4	1	5
56.	Malta	2	-	2
57.	Mauritius	1	-	1
58.	Mexico	6	5	11
59.	Montenegro	2	-	2
60.	Morocco	1	-	1
61.	Myanmar	2	-	2
62.	Namibia	1	-	1
63.	Netherlands	2	1	3
64.	New Zealand	1	-	1

65.	Nicaragua	1	-	1
66.	Nigeria	1	-	1
67.	Norway	1	-	1
68.	Oman	3	-	3
69.	Pakistan	2	-	2
70.	Palestinian Territory	1	-	1
71.	Panama	2	-	2
72.	Paraguay	2	-	2
73.	Peru	5	-	5
74.	Philippines	3	-	3
75.	Poland	4	7	11
76.	Portugal	5	1	6
77.	Puerto Rico	1	1	2
78.	Qatar	3	-	3
79.	Romania	11	-	11
80.	Russia	5	2	7
81.	San Marino	2	-	2
82.	Saudi Arabia	3	1	4
83.	Serbia	5	-	5
84.	Singapore	3	2	5
85.	Slovakia	2	1	3
86.	Slovenia	3	1	4
87.	South Africa	2	1	3
88.	South Korea	10	9	19
89.	Spain	9	9	18
90.	Sweden	1	1	2
91.	Switzerland	6	2	8
92.	Taiwan	6	4	10
93.	Thailand	4	2	6
94.	Turkey	6	3	9
95.	Ukraine	4	-	4
96.	United Arab Emirates	6	-	6
97.	United Kingdom	4	3	7
98.	United States	18	25	43
99.	Uruguay	1	-	1
100.	Venezuela	5	-	5
101.	Vietnam	3	3	6
102.	Zimbabwe	1	-	1
Total		**352**	**174**	**526**

C*ompiled from: https://parentsguidecordblood.org/en/family-banking/*
https://parentsguidecordblood.org/en/public-banking/

Bart (2010) examined the number of cord blood banks with regards to the population of the country (Table 3). The United States had the greatest factor of 40.4 about ten times more than the closest rivalry German. The factor is a reflection of government commitment to the development of the cord blood industry.

Table 3: Worldwide Comparison of Public Cord Blood Banking Relative to Country Population

Country	Population	Factor	CBUs blanked	Population/CBU
Switzerland	7,604,467	1	2,750	2,765
Germany	82,329,758	10.8	23,502	3,503
United State	307,212,123	40.4	172,614	1,780
Australia	21,262,641	2.8	22,258	955
France	64,420,073	8.5	8,807	7,315
Italy	58,126,212	7.6	20,463	2,841
Belgium	10,414,336	1.4	14,057	741
United Kingdom	61,113,205	8.0	11,217	5,448
Netherlands	16,715,999	2.2	2,841	5,884
Spain	40,525,002	5.3	44,402	913

Note: Factor refers to the relation of the respective population to the Swiss population, where the factor for Switzerland is 1.
Source*: (*Bart, *2010)*
Bart (2010) also reported the progress of cord blood banking worldwide from 1999 to 2010. The available and provided CBUs developed progressively from 1999 to 2009 (Table 4)

Table 4: Worldwide Development of Cord Blood Banking (1999-2009)

		1999	2000	2001	2003	2004	2005	2006	2007	2008	2009	Cum.
CBUs available	44,000	70,000	105,000	136,000	181,000	229,000	256,000	292,000	406,000	452,000	537,000	
CBUs provided	462	508	691	848	1,467	1,740	2,336	2,671	3,393	3,522	3,749	21,387
Percentage provided	1.05%	0.73%	0.66%	0.62%	0.81%	0.76%	0.91%	0.91	0.84%	0.78%	0.70%	3.98%

Source:(Bart, *2010)*

Cord Blood Laboratories in Africa

Next Biobank Africa's largest stem cell laboratory is located in South Africa. Next Biobank processed and stored its first cord blood sample in December 2006 and to date has stored over 18,000 samples from South Africa, Kenya, Namibia, Zimbabwe and Mauritius (https://parentsguidecordblood.org/en/bank_locations/netcells-nigeria).

Accreditations of Umbilical Cord Blood Banks

Internationally accepted and recognized accreditations are important for a cord blood bank. Accreditations certify that the blood bank has been appraised by authorized bodies for competency, credibility, operational efficiency, and quality management of processing and cryopreservation protocols to ensure the safety of the umbilical cord blood stem cells that are being preserved. Accreditations are also quality standards. To ensure success and the true realization of the full potential of CB, whether for autologous or allogeneic use, Each product provided for current and future treatments must meets international standards (Armitage, 2016).

It is standards for CB banking must be international, since CB products frequently cross international borders (Armitage, 2016). Units, that do not meet cord blood standards for clinical use may be used for quality improvement or research if parents give consent to do so. Only about 25–40% of the UCB collected by Public Cord Blood banks meet these criteria (Guilcher *et al*., 2015).

With the increased clinical use and exchange for these UCB units it became necessary to standardize practices across the various CBBs. To contribute to this, a group of experts involved in UCB banking established the NetCord organization in 1998 (Wernet, 2004).

The Foundation for the Accreditation of Cellular Therapy (FACT) was founded in 1996 by the American Society for Blood and Marrow Transplant and the International Society for Cellular Therapy to establish standards and a voluntary inspection and accreditation program for quality patient medical care and laboratory practice in haematopoietic cellular therapy, while preserving the essential research environment.

The Foundation for the Accreditation of Cellular Therapy (FACT) collaborated to develop international standards for cord blood banking with NetCord, a foundation of member cord blood banks established to globally unite the supply and demand of umbilical cord blood and to maintain worldwide standards and a system of quality approval in the area of umbilical cord blood. The goals of NetCord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release are to promote quality practices and to consistently assure the provision of quality cord blood units for transplantation (Wernet, 2004; NetCord-FACT, 2013).

Initially and to make the best use of resources, consent was only obtained from mothers from whom a successful collection had been obtained. However, in Europe following the implementation of the European Union Tissues and Cells Directive (EUTCD) 2004/23/EC in 2006, stating that "procurement of human tissues or cells shall be authorized only after all mandatory consent or authorization requirements have been met," all collected UCB units need to have a signed consent obtained prior to delivery (Kidane *et al*., 2007).

Since CBB and UCB transplantation activities involve the import and export of cellular product across different countries, they need to operate within a highly regulated environment (Navarrete, 2015). The regulatory aspects covering the activity of CBB have increased significantly since the first UCB transplant. In the European Union, the EU Directive 2006/17/EC and 2006/86/EC regulate the quality and safety issues covering the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells (Kidane *et al*., 2007).

In the United States, the Food and Drug Administration (FDA), 2005 introduced the regulation of the manufacture of unrelated UCB to support compliance with the Current Good Tissue Practices 21 CFR 1271.210. Later on, in 2007 the FDA issued a draft guidance recommending the licensure of CBB for the manufacture of UCB units. This was finally implemented in 2011 and requires that all manufacturers of UCB units need to have an approved Biologics License Application or Investigational New Drug Application to be able to import a UCB into the United States. This regulation treats a UCB unit as a biological drug.

The basis for accreditation is to show documented compliance with the current edition of the standards. Accreditation establishes a uniform level of practice and promotes high-quality products/practices, leading to improved patient outcomes and elevates the bank's position as a quality organization and informs patients, health insurance companies, and governments that their organization is dedicated to excellence in the patients' care and laboratory practices.

Accreditation provides evidence of external validation through on-site inspections and facilitates the establishment of quality management and process control to minimize liabilities and regulatory non-compliance. Accredited organizations voluntarily seek and maintain accreditation through a rigorous process, demonstrating their belief that the patients' needs are paramount (Kidane *et al*., 2007).

The primary optional accrediting agency for cord blood banks is the Association for the Advancement of Blood and Biotherapies (AABB). The Association for the Advancement of Blood and Biotherapies (AABB) is an international, not-for-profit association representing individuals and institutions involved in the field of cellular therapies and transfusion medicine formed in 1947. In 2005, the organization changed its name from the American Association of Blood Banks to Association for the Advancement of Blood and Biotherapies to reflect the changes in scope and operations (Loper *et al*., 2005).

In the United States, public cord blood banks are required to get a Biologics License from the FDA, but family cord blood banks are only required to register with the FDA and undergo surprise inspections. The FDA governs all aspects of cord blood preservation, including the collection, processing, storage, labeling, packaging, and distribution of cord blood stem cells.

While optional, AABB accreditation is considered one of the leading global credentials that a cord blood bank can hold. Parent's Guide to Cord Blood Foundation recommends that parents choose a family bank that has AABB or FACT accreditation, if one is available in your country. While based in the U.S., the organization is international in reach, with members in 80 countries. It has taken on a broader scope to include all of the transfusion, as well as cellular therapies, including ones based on haematopoietic stem cells. For this reason, AABB accreditation has great significance within the cord blood banking sector.

Cord blood laboratories that are located in certain countries are required by federal law to follow high standards: these include GMP in Germany, HTA in the UK, Swiss medic in Switzerland and TGA in Australia.

Association for the Advancement of Blood & Biotherapies (AABB) and FACT are the only voluntary accreditations that are specifically designed for cord blood laboratories, thus are considered to be the gold standards.

As of January 1, 2014, there were only 18 countries with 67 AABB accredited facilities. By March 2015 there were 76 AABB accredited cord blood banks worldwide, an increase of 9 facilities since January 1, 2014 (Hildreth, 2015). Of the 76 total accredited cord blood banks worldwide, 29 are located within the United States, again asserting the relatively mature nature of cord blood banking industry within the United States, as compared to other parts of the world (Figure 2).

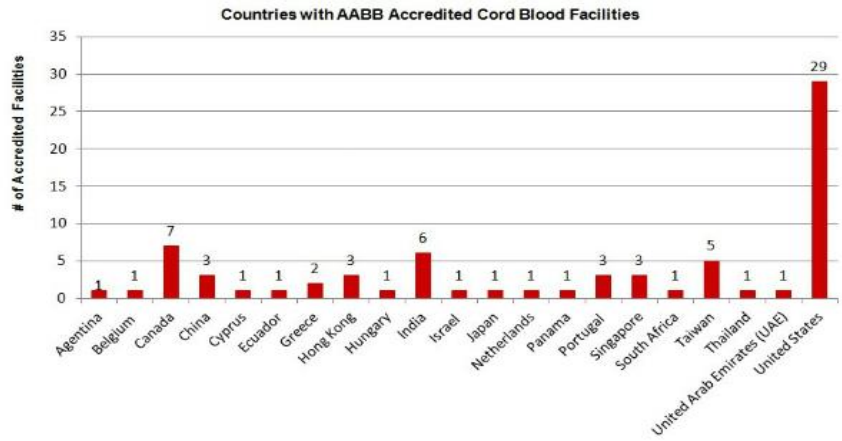

Figure 2: Countries with AABB Accredited Cord Blood Facilities
Source: Hildreth, *2015*

CONCLUSION

There are different reasons for cord blood storage ranging from an immediate need within the family to treat a disease amenable to transplantation to a woman or a couple donating altruistically (as with blood donation) by offering the cord blood as a public resource to be available for others with the need for an immediate transplant and finally for research purposes.

Umbilical cord blood gifted to non-profit public cord blood banks is now routinely used as an alternative source of haematopoietic stem cells for allogeneic transplantation for children and adults with cancer, bone marrow failure syndromes, haemoglobinopathies and many genetic metabolic disorders. The increasing demand for UCB led to the establishment of cord blood banks, where the blood is cryopreserved and stored for future recipients.

Accreditations certify that the blood bank has been appraised by authorized bodies for competency, credibility, operational efficiency, and quality management of processing and cryopreservation protocols to ensure the safety of the umbilical cord blood stem cells that are being preserved. AABB is the world leading UCB accrediting body. While optional, AABB accreditation is considered one of the most important global credentials that a cord blood bank can hold.

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