

Impact of Selection of Cord Blood Units from the United States and Swiss Registries on the Cost of Banking Operations

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Summary

Background: Over the last 2 decades, cord blood (CB) has become an important source of blood stem cells. Clinical experience has shown that CB is a viable source for blood stem cells in the field of unrelated hematopoietic blood stem cell transplantation. **Methods:** Studies of CB units (CBUs) stored and ordered from the US (National Marrow Donor Program (NMDP) and Swiss (Swiss Blood Stem Cells (SBSC)) CB registries were conducted to assess whether these CBUs met the needs of transplantation patients, as evidenced by units being selected for transplantation. These data were compared to international banking and selection data (Bone Marrow Donors Worldwide (BMDW), World Marrow Donor Association (WMDA)). Further analysis was conducted on whether current CB banking practices were economically viable given the units being selected from the registries for transplant. It should be mentioned that our analysis

focused on usage, deliberately omitting any information about clinical outcomes of CB transplantation. **Results:** A disproportionate number of units with high total nucleated cell (TNC) counts are selected, compared to the distribution of units by TNC available. Therefore, the decision to use a low threshold for banking purposes cannot be supported by economic analysis and may limit the economic viability of future public CB banking. **Conclusions:** We suggest significantly raising the TNC level used to determine a bankable unit. A level of 125×10^7 TNCs, maybe even 150×10^7 TNCs, might be a viable banking threshold. This would improve the return on inventory investments while meeting transplantation needs based on current selection criteria.

Introduction

The transplantation of bone marrow has developed considerably since the first publication of results in 1957 by Thomas et al. [1]. In the year 2010, almost 17,000 products were provided for allogeneic transplantation worldwide for unrelated pa-

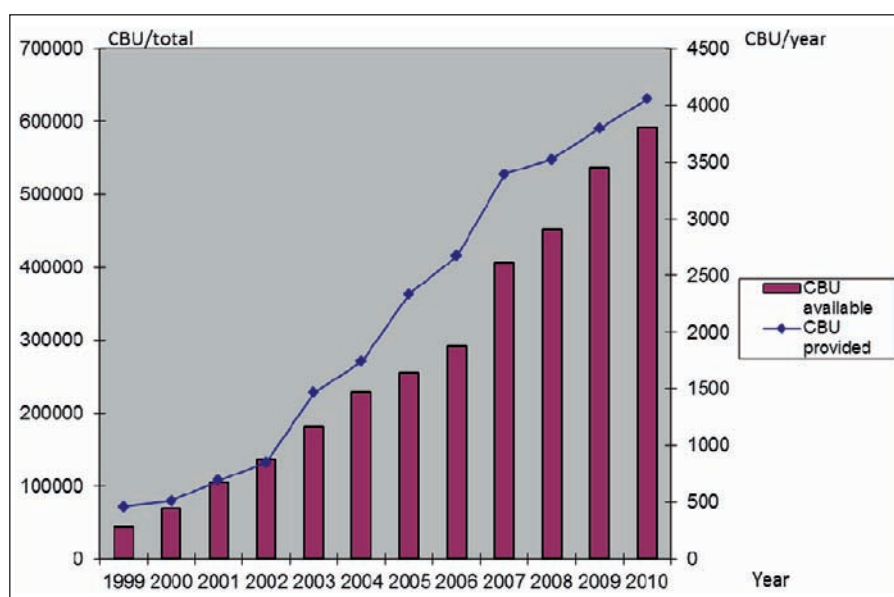


Fig. 1. Development of worldwide unrelated CB banking (data source: WMDA).

tients with oncologic, genetic, hematologic, and immunodeficiency disorders (3,574 bone marrow units, 9,248 peripheral blood stem cell (PBSC) units, 4,054 cord blood units (CBUs)) [2, 3].

Over the last 2 decades, umbilical cord blood (CB) has become an increasingly important source of blood stem cells. Clinical experience has shown that CB is a viable source for blood stem cells in the field of unrelated hematopoietic blood stem cell transplantation [4]. In 1989, the first CB transplantation was reported in a boy suffering from Fanconi anemia; the first two series of CB transplantation from related and unrelated donors were reported in 1994 and 1995 [for review see 5]. The first unrelated CB banking programs were started in 1992 at the Eurocord/Netcord Bank in Düsseldorf [6] and in 1993 at the New York Blood Center [7].

The global inventory of CBUs available grew from less than 100,000 CBUs in 2000 to almost 600,000 at the end of 2010, stored in more than 140 CB banks worldwide (fig. 1) [2, 3]. Worldwide, CB has become the second most important source of blood stem cells after PBSCs and before bone marrow (2010 World Marrow Donor Association (WMDA) data). Some 25% of all hematopoietic blood stem cell donations worldwide are performed using CB [2, 3].

The most relevant advantages of CB as a source of hematopoietic stem cells are the relative ease of procurement, the absence of risks for mothers and donors, the reduced likelihood of transmitting infections, particularly cytomegaloviruses, and the ability to cryopreserve fully tested and human leukocyte antigen (HLA)-typed stem cells, available at short notice [8]. Disadvantages include: slower engraftment, more frequent graft failure, less graft-versus-host disease and possibly less graft-versus-leukemia effect, and more infections [4, 5, 9].

Economic Analysis

Evaluating the costs of handling different blood stem cell sources is complex. Majhail et al. [10] found in 2010 that costs of matched unrelated donors and CBUs are similar when costs of graft acquisition were considered within the total costs of transplantation.

However, other studies show significant economic differences between CB on the one hand and bone marrow and PBSCs on the other. Costs of procuring CBUs are possibly more than 10 times higher than the costs of bone marrow or PBSCs, mainly due to the fact that the overwhelming majority of the more than 500,000 CBUs in the past 10 years have not been used and are unlikely ever to be used. As such, the costs for processing and storing these CBUs could be regarded economically as ‘sunk costs’ [11]. These units may have some value in the future for research or should expansion technologies become clinically available.

Another reason is the high discard rate of CBUs before cryopreservation [12]. Lauber et al. [13] reported in 2010 for the Mannheim Cord Blood Bank that only about 25% of all collected CBUs met storage criteria. The main reasons for exclusion were insufficient volume, delayed time to processing, and low cell count.

In 2005, Kurtzberg et al. [12] described data from the Cord Blood Transplantation Study (COBLT). From a total of 17,207 units that were collected between 1998 and 2001, 11,077 units were cryopreserved and quarantined. Of these, only 8,750 units (50%) met eligibility criteria, were HLA-typed and entered into the search registry. Other authors report high deferral rates as well: Lecchi et al. [14] with Italian data, Stanworth et al. [15] in an international and Troeger et al. in a Swiss survey [16], ranging from 20 to 90%.

One of the more important criteria for CBU selection is the total nucleated cell (TNC) count of the unit. CBUs with

an increased TNC count and those more recently collected were more likely to be ordered for transplantation. One explanation for this is the increasing use of CBU transplantation in adults. (The average adult in the USA weighs approximately 75 kg. Assuming a minimum dose of 2.5×10^7 TNCs/kg, a unit of approximately 188×10^7 TNCs is necessary as a minimum for transplantation.) Studies report a direct correlation between patient size and CBU TNCs, emphasizing the need to maximize the TNC count, especially when a mismatched unit is selected [17].

Data from Australia, Germany, and Korea support this finding, showing that transplanted CBUs have higher mean numbers of TNCs than stored CBUs [13, 18, 19]. Gragert et al. [20] concluded in 2011 that CB banks may want to focus more on adding CBUs with a high TNC rate rather than aiming for large overall increases in CBU inventory. Querol [21] came to a similar conclusion, noting that a focus on adding more units alone may not be a sustainable strategy for CB banking. Clark et al. [18], in 2011, identified these facts as risks for the CB inventory.

Based on data from the Mannheim Cord Blood Bank [13], the median TNC count of CBUs shipped was 119×10^7 , while the median TNC count of CBUs in inventory was 65×10^7 .

Medical and Economic Implications

The high cost of CB handling has medical and economic implications. To overcome the limitation of cell dose per CBU, infusion of 2 CBUs was adopted as a new transplantation strategy a few years ago. However, one limitation of double CB transplantation is the high costs of the 2 CBUs [22].

The high costs have consequences for global public CB banking, mostly because public or external funding is scarcer in today's economic climate and a continuation of the previous banking strategy is not financially sustainable in the medium term. In the long term, a collapse of individual banks and maybe even the whole system is possible.

In light of these concerns, this paper examines 2 questions: First, are public banks using the right criteria for selecting CBUs to bank and, second, is the current model of banking financially sustainable?

Material and Methods

Selection of CBUs

An analysis of the unrelated CB registries maintained by the National Marrow Donor Program (NMDP) in the USA and the Swiss Blood Stem Cells (SBSC), a unit of Transfusion SRC Switzerland, was performed to identify which CBUs were being selected for transplantation from these registries and whether the selection practice has changed over time. The study looked at the total number of CBUs being added to the inventory from 2006 through 2010, divided into subsets by TNC count.

The analysis then looked at the selection of CBUs for transplant each year and divided them into comparable TNC cohorts. This was compared to the same data reported by the Bone Marrow Donors Worldwide (BMDW).

Table 1. Financial implications of public CB banking

	Industry year 1
Beginning inventory	145,000
Number of cord units recruited	89,187
Cost to recruit per unit, USD	206
% Banked (processed as % of recruited)	33
Number of cord units processed	29,234
Cost to process per unit, USD	886
Cost to recruit and process, USD	1,524
% Cord units distributed	1.16
Number of cord units distributed	1,682
Cost to distribute per unit, USD	616
Total average overhead cost per unit processed, USD	505
Cost to store 1 CBU for 1 year, USD	27
Average distribution price, USD	30,358
Cost to recruit, USD	18,398,924
Cost to process, USD	25,993,499
Cost to distribute, USD	1,036,716
Cost of overhead (fixed at baseline levels), USD	14,798,094
% Overhead of all cost	23.08
Cost to store, USD	3,902,943
Total cost, USD	64,130,176
Total revenue, USD	51,062,396
Net cash flow – excluding subsidies, USD	13,067,780

Financial Viability of Banking

Separately, the NMDP surveyed 4 CB banks in the USA on the costs of operating a CB bank. Information obtained included cost of supplies, equipment and labor associated with the recruitment, collection, transportation, processing and storage of CBUs for public use. Indirect expenses were also estimated.

The CB banks represented a variety of settings, including academic medical centers, blood banks, and free-standing centers, as well as a variety of collection methods including collections by obstetrical volunteers, by paid staff, and by a mix of the two. When all costs were included, the average cost of recruitment, collection, banking, and storage for each unit actually stored was USD 1,830.00, including costs of units that were collected but not banked due to a variety of reasons, including failure of testing, below bankable size, etc. These data were averaged across all banks, and an estimate of indirect expenses and overhead was included based upon additional data provided by the banks.

The data collected by the NMDP were then combined and reformatted to create a generic CB banking operation. Cost elements were confirmed through interviews with the banks to establish as best as possible that all costs were identified. The NMDP categorized the costs based on its own model.

A similar analysis was conducted by SBSC in the year 2005. This analysis showed costs for collection, processing and banking for CBUs of approximately CHF 2,500.00 per banked unit. Taking inflation rate and the recent variability of currency exchange rates into account, the US and the Swiss costs appear comparable, adjusting for differences in purchasing power parity of the 2 countries, which showed in 2010 an over-valuation of the Swiss franc of 66% in comparison to the US dollar [23].

The banking model developed by the NMDP was then used to assess the business of CB banking in the USA based on the current demand from the US market and the current inventory available in the USA. The US market demand was determined by comparing NMDP data with the data available through the WMDA, to estimate the number of CBUs used in the USA in 2010. Total available inventory was assumed to be in-

Table 2. Comparison of US and Swiss CB inventories, distribution by TNC count^a

USA				Switzerland			
TNC	CBU	% total	% cumulated	TNC	CBU	% total	% cumulated
< 125	98,126	68.54	69	< 125	2,248	71.94	72
125–149	22,146	15.47	84	125–149	406	12.99	85
150–174	11,517	8.04	92	150–174	217	6.94	92
≥ 175	11,371	7.94	100	≥ 175	254	8.13	100
Total	143,160	100.00		Total	3,125	100.00	
< 125	98,126	68.54	69	< 125	2,248	71.94	72
≥ 125	45,034	31.46	100	≥ 125	877	28.06	100
Total	143,160	100.00		Total	3,125	100.00	

^a2010 data.

ventory listed on the NMDP registry plus an estimate of inventory available outside the NMDP registry, but located within the USA. For purposes of the analysis, it was assumed that all units used in the USA for unrelated CB transplant were selected from this national inventory. Based upon data reported from the banks, it assumed the price of each unit used in transplant to be USD 30,358.00. Data for the year 2010 can be seen in table 1.

Results and Discussion

Medical Aspects

Selection of CB units for transplant is based on 2 primary characteristics of a CBU. It must meet the HLA matching requirements of the transplant center (typically no less than 4 of 6 based upon antigen level matching for A and B and allele level matching for DRB1), and it must meet minimum cell dose requirements (TNC count).

NMDP data shows that, in selection of a CBU for an adult, a 4-of-6 unit will be selected 57% of the time. Therefore, dose becomes a critical factor. Wagner et al. [17] even suggest that the choice of a CBU should be based primarily on cell dose and only secondly on HLA matching.

The increasing use of 2 CBUs in a single transplant has likely contributed to the increase in the number of CB transplants performed in adults. Selection of units for double transplant from the NMDP inventory shows that units selected tended to be the larger units in the inventory and have been relatively equal in size. This may be due to the need to obtain at least the minimum dose or the uncertainty of which unit will engraft. As a result, in the majority of double-CBUs shipped through the NMDP in 2010, the difference between the 2 units selected is less than 20×10^7 TNC.

Units Banked

Figure 2 and table 2 show the current units banked in the NMDP and SBSC registries, arranged by TNC cohorts, alongside similar data from the BMDW inventory. The number of banked units is significantly weighted to the smaller end of the scale.

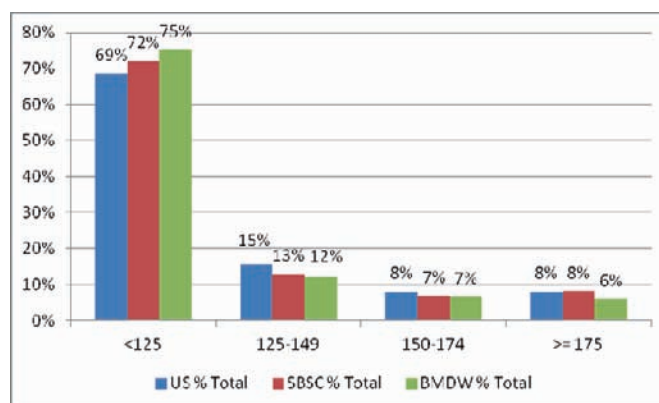


Fig. 2. Inventory distribution by TNC count (US/NMDP, Swiss/SBSC and international/BMDW data 2010).

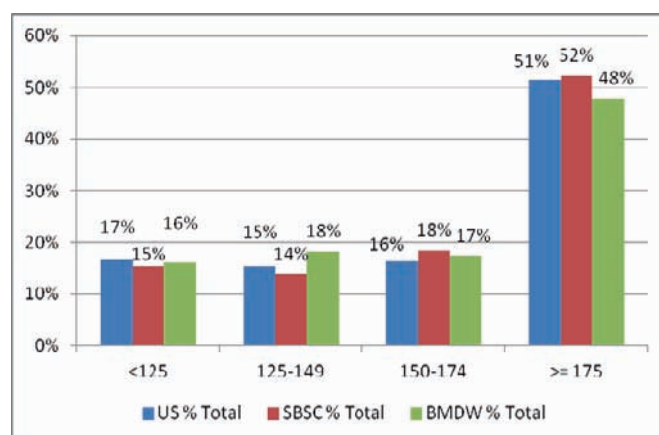


Fig. 3. Selection distribution by TNC count (2010 BMDW data).

Units Selected

While banking inventories are heavily weighted to smaller CBUs, units selected for transplant are weighted to larger CBUs. For instance, in the NMDP inventory, the median TNC count of the inventory is 104×10^7 and the median of units shipped is 176×10^7 . Figure 3 and table 3 show the selection by transplant centers of units from the NMDP and SBSC registries and the units provided globally reported to the BMDW.

Table 3. Comparison of US and Swiss CBUs selected, distribution by TNC count^a

USA				Switzerland			
TNC	CBU	% total	% cumulated	TNC	CBU	% total	% cumulated
< 125	200	16.75	17	< 125	10	15.38	15
125–149	184	15.41	32	125–149	9	13.85	29
150–174	197	16.50	49	150–174	12	18.46	48
≥ 175	613	51.34	100	≥ 175	34	52.31	100
Total	1,194	100.00		Total ^b	65	100.00	
< 125	200	16.75	17	< 125	10	15.38	15
≥ 125	994	83.25	100	≥ 125	55	84.62	100
Total	1,194	100.00		Total ^b	65	100.00	

^a2010 data.
^bCumulated.

Table 4. Likelihood of CBUs to be used over a 5-year period^{a,b}

Cumulative % shipped	Years in inventory					
	year 0 ^c	year 1 ^d	year 2	year 3	year 4	year 5
Total % shipped	1	2	4	6	7	8
TNC 125 or greater, %	1	4	9	12	15	16
TNC 150 or greater, %	2	7	13	17	20	22
TNC 175 or greater, %	2	9	16	22	27	29

^aNMDP data.
^bDistribution rates by TNC count for inventory banked in calendar year 2005.
^cYear in which the unit was added to the inventory.
^dFirst year after the unit was added to the inventory.

In 2010, 1,194 CBUs were shipped out of the available US inventory of 143,160 CBUs, resulting in a yearly distribution rate of 0.8%. The 65 Swiss units that were cumulatively shipped out of the 3125 available Swiss CBUs in inventory at the time resulted in a cumulated distribution rate of 2.1%. These shipments served both pediatric and adult patients. Based on this banking and distribution pattern, the vast majority of the CB inventory would remain unused, based on current indications.

Data from the NMDP shows that 68% of all CBU shipments for adults in 2010 had a TNC count of over 150, compared to 65% in 2005. Furthermore, data shows that 28% of all CBUs had a TNC count of less than 90, but only 3% of units shipped were from that group. 40% of the inventory was in the 90–124 group compared to 13% of all units shipped.

Thus, 69% of the inventory had a TNC count of less than 125, yet only 17% of all units shipped came from that group. 83% of all CBUs shipped in 2010 had a TNC count of greater than 125 and came from 31% of the available inventory.

At SBSC, the numbers are similar: More than 50% of shipped CBUs have a TNC of more than 175, but only 8% of the currently stored CBUs have this value. 85% of the shipped CBUs show a TNC of above 125, but only 28% of the currently stored CBUs have this value.

Altogether, the comparison of US, Swiss and international data shows a striking resemblance in the relationship between CBU inventory and shipments as well as TNC count.

Likelihood of a Unit to Be Used

The NMDP examined its records to determine the likelihood that a unit would be used for transplant over a 5-year period based upon the TNC count of that unit. Looking at the base year of 2005 and examining the actual selection from the inventory by each TNC cohort, table 4 shows the likelihood that a unit will be used out of each cohort over the 5-year period.

Actual selection data demonstrates that a unit with a TNC count of 125 or greater will likely be selected at 16% of the time over a 5-year period, while a unit of at least 175 or greater will be selected at 29% of the time over a 5-year period, both these compared to a likelihood of 8% of the total.

Financial Implications

The average cost of each unit banked increases with the use of a higher TNC count, because the discard rate of units collected but not banked increases with the higher TNC count. On average, 3 units will be collected for each unit processed at a cut-off at TNC 90, while 13 units will be collected for each unit processed at a cut-off of TNC 150 (NMDP data based on statistics collected from the 4 CB banks interviewed for the model). The average costs to collect a unit for processing at a cut-off of 90 is: 3 × USD 206.00 (= USD 618.00), while the costs to collect a unit at a cut-off of 150 is: 13 × USD 206.00 (= USD 2,678.00).

Table 5. NMDP CB inventory: Cost of banking (total) and shipment (per CBU), distributed by TNC^a

TNC count ($\times 10^7$)	Recruited	Estimated cost to collect, process and bank, USD	Shipments	Cost per shipment, USD
<90	47,730	71,595,000	323	221,656
90–124	67,720	101,580,000	1,069	95,023
125–149	26,902	40,353,000	1,044	38,652
150–174	14,704	22,056,000	1,080	20,422
175–199	7,789	11,683,500	922	12,672
200–224	4,050	6,075,000	775	7,839
225–249	2,159	3,238,500	532	6,087
250–274	1,169	1,753,500	372	4,714
275–300	624	936,000	200	4,680
>300	794	1,191,000	348	3,422
Total	173,641	260,461,500	6,665	39,079

^aVariable cost to process and bank estimated at USD 1500 per unit, historical shipments through February 2011, all CBUs ever recruited, through February 28, 2011.

Translating this into an industry model, the increase in TNC threshold on an industry-wide basis will significantly reduce the growth rate in the available public CB bank inventories, but will not significantly impact the utilization of CBUs out of those inventories, firstly because the units preferred by the transplant centers will continue to be banked and secondly because there remains a significant inventory of smaller units that still retains potential clinical utility.

Table 5 summarizes all units that have been added to the NMDP inventory by TNC cohort, as well as all shipments by TNC cohort.

Assuming an average variable cost to collect and process of USD 1,500.00 per unit, the table shows the excessive actual cost of banking units below 150×10^7 TNC based on utilization. The cost of banking those units can never be recovered based on the current usage patterns. The table clearly illustrates that, for units below 125 TNC, there is a disproportionate relationship between a high inventory and a low utilization rate. The average cost of these units is in the range of USD 95,023.00–221,656.00 per CBU to collect, process and cryopreserve. The processing cost of those CBUs with very low utilization rates is mainly responsible for the current high cost of public CB banking. Even units with a TNC count between 125 and 149 are prohibitively expensive to bank as their cost to collect, process and cryopreserve ranges at USD 38,652.00, which is significantly higher than most CB banks charge for a unit.

A concern often expressed is that expansion might bring higher utilization rates to smaller units. If expansion proves clinically effective, indeed:

- banks have many units in inventory that can now become useful and that is truly where the HLA diversity of the CB registry is, and
- if there is an increase in demand, banks will be able to ramp up banking activity almost immediately.

Conclusions

The experience of the US and Swiss CB registries shows a similar pattern of banking and use when comparing TNC counts. The inventories of these registries are disproportionately weighted to smaller CBUs when compared to units actually selected. This has significant economic consequences on the public CB banks, which have expended substantial resources on units unlikely to be selected. The global database, BMDW, and the WMDA annual reports confirm this observation.

Current banking practices using comparatively low minimum TNC numbers as a threshold for banking appear not to be sustainable. Increasing the threshold rate will result in a sustainable banking model, assuming the commitment of current resources to collection and banking, while at the same time assuring that the units preferred for transplant will continue to be banked at the same or higher rates. At the present level of knowledge, a level of at least 125×10^7 TNC, maybe even 150×10^7 TNC, might be a viable banking threshold. For a successful implementation of this fundamental change in banking strategy, it is necessary, in addition to purely technical adjustments of locally relevant banking regulations, to include all key stakeholders (especially harvesting/collection centers, gynecology departments, but also expectant mothers) in integrated communication and information measures, to explain the rationale and the background of the changes to come.

Disclosure Statement

The authors declare to have no financial or non-financial conflict of interest to disclose.

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