Cost Accounting for Hematopoietic Stem Cell Transplantation

–Based on Tentative Cord Blood Cost Accounting Guideline–

Kenjiro Ide

1. Backgrounds – Hematopoietic stem cell transplantation –

1.1. Hematopoietic stem cell transplantation

Hematopoietic stem cell transplantation is a treatment for patients who suffer from severe illnesses that prevent them from making normal blood cells, such as aplastic anemia and leukemia. In this treatment, the donor’s hematopoietic stem cells are transferred to the patient, and enable them to create own normal blood cells.

Hematopoietic stem cells have been confirmed to exist in bone marrow, peripheral blood, and cord blood. Consequently, there are three types of hematopoietic stem cell transplantation: bone marrow transplant, peripheral blood stem cell transplant, and cord blood transplant. Induced pluripotent stem cells (iPS cells) have been widely discussed, but the hematopoietic stem cell transplantation has also been garnering a lot of attention as a part of regenerative medicine.

The Liberal Democratic Party Health and Labor Task Force’s proposed bill designed to standardize hematopoietic stem cell transplantation is one sign of this attention. There is a possibility that the bill will be submitted to the National Diet as early as next session.

This article discusses the cost of cord blood used in hematopoietic stem cell transplantation. At first glance, it may seem as simple as “What is the cost of blood?” but as this article will show, when the issue of cord blood is examined in detail, it is clear that there needs to be a structure for costing.

1.2. What is Cord Blood?

The umbilical cord is a part that connects the mother (Mother) to the fetus (Baby or Embryo). The blood in the umbilical cord and the placenta is called cord blood or umbilical cord blood. As explained above, like bone marrow, inside cord blood are hematopoietic stem cells that have the ability to create new blood cells. Thus, cord blood has many uses in treatments for serious incurable or genetic blood related illnesses, such as leukemia. Cord blood transplant cases have been rising, and now there are as many or more cases as for bone marrow transplant.

1.3. The Process of Cord Blood Transplant

Just as there is some processes to manufacture products, there is a series of steps from collecting cord blood to transplanting the cord blood into the patient.

① Collecting and Delivering Cord Blood

Cord blood is collected at the time of birth. However, every gynecology department or hospital is not able to collect cord blood. Cord blood is collected outside the body unlike bone marrow or peripheral blood. It may be afraid of high risk of being contaminated. That is why cord blood is only collected at medical collection facilities (cord blood collection affiliated hospitals).

The mother’s permission is required whether the cord blood can be donated (i.e., whether it would
After the cord blood is processed, there are several additional measurements conducted before the blood is donated, including a blood cell count, viable cell count, and the colony recovery rate.

In addition, NAT testing and, as previously mentioned, HLA tests, are conducted before the cord blood is donated. NAT stands for Nucleic acid Amplification Test. In this test, a portion of the nucleic acid from genetic material is extracted, and then increased several times over. The amplified nuclear acid is then used to test for the presence of specific genetic components.

Cord Blood Donation and Transplantation

At the point information about the cord blood is released publicly, the cord blood is already ready to be donated. Thus, as soon as there is a request, cord blood that has passed the testing in is donated to the transplantation medical facility. That is, the cord blood is transported and then transplanted.

2. The Operating Problems for Cord Blood Banks Programs (the Saitaiketsu Bank)

2.1. Problems with Accounting and Costing for Cord Blood Bank

There is a need to properly account the cost given for being cord blood important. Until now, there had not been a clear answer to the question “How much does it cost to process cord blood to be donated.” Furthermore, there had not been any thought paid to the cost of cord blood.

Previously, the amount spent on cord blood was actually treated as expenses for that period. Thus, because it was recognized as an expense, on the balance sheet, cord blood as a “thing” did not exist off balance. There are several reasons are following.

(1) Accounting standards were not well developed

The accounting standards on Japanese Red Cross Society (Japanese Red Cross Accounting Principles or related to cord blood) Blood Pro-
programme Specific Accounting Principles) were not in line with generally accepted accounting principles (shortly mentioned GAAP). They were essentially like budget or cash based income and expenditure calculations (cash based accounting).

(2) Financing depended on Aid

Cord blood donation is not something that can utilize a self-supporting accounting system. Because of its importance, government involvement and financial aid is necessary. It is also important to consider the intent of the aid, however, and make sure that the received aid is spent appropriately, neither paying too much nor too little.

(3) The Lack of Cost Consciousness

Although this is generally related to the financial aid system, it is clear that those involved in cord blood donation focused on studying cord blood itself, neglecting the cost side. Because of this focus on research, issues surrounding the cost of cord blood had necessarily taken second place to the development of regenerative medicine. However, accounting term in 2010, the cord blood banks affiliated the Japanese Red Cross, and other cord blood banks were in the red and realized losses.

2.2. Launch of the Japanese Red Cross Society “Cord Blood Program Research Committee”

In January 2010, the Japanese Red Cross Society launched the “Cord Blood Bank Program Research Committee” (chaired by Kazuo Kawahara, Professor at Tokyo Medical and Dental University) to decide the future direction of the Japanese Red Cross affiliated cord blood bank programs (6 banks). Cord Blood Program Research Committee is a parent committee over two working groups. One is the Technology Committee (chaired by Noriko Takanashi, Japanese Red Cross Society Tokyo Section Medical Products Section Chief), tasked with developing guidelines and methods that protect product quality of cord blood from collection to donation. The other is the Accounting Committee tasked with developing accounting guidelines (chaired by Kenjiro Ide).

The Accounting Committee’s main mission is to develop guidelines for preparing for financial statements related to cord blood banks based on accounting standards, and how to account the cost of cord blood (total cost). In April 2012, Japanese Red Cross Accounting Principles and the Japanese Red Cross Blood Society Programme Specific Accounting Principles changed significantly, thus the standards that underlie preparing financial statements for the cord blood banks needed to be changed as well.

The Japanese Red Cross Society and the Blood Programme Specific Accounting Principles adopted an accounting system based on the corporate accounting system, which requires basic financial statements, such as an income statement, a balance sheet, and cash flow statement based on GAAP.

In the process of establishing and adjusting the accounting standards, there has been a paradigm shift underlying the relationship between the cord blood program and financial statements. For the first time in the history of the Japanese Red Cross Society, cord blood is listed as an asset on the balance sheet (balance sheet). This is based by the theory that cord blood has “service potential.” Thus the expenses incurred in collecting and preparing cord blood will be matched in some future service, which means that cord blood is an “asset.” There are a number of problems on how to evaluate the stored cord blood. The evaluation of cord blood as an asset will be expected to have a positive impact on the cord blood programs.

3. Tentative Cord Blood Cost Accounting Guideline

Recently, cord blood has to be recognized and measured a fair value based on sales or market
value in order to evaluate it as an asset. In traditional accounting theory, the asset value of a product is generally matched the sum of the expenditures incurred in manufacturing that product (treated as the cost). Cord blood as a "product" is the same. The expenses incurred until the cord blood is prepared become part of the cost, and that cost is considered the valuation of cord blood as an asset. There are several discussions about what the cost of cord blood is. Of course, the method of costing is an internal issue for organizations, and the Japanese Red Cross Society is not an exception.

As previously stated, however, as part of the process in implementing the possible "Law on hematopoietic stem cell transplant" and other measures, there need to be standards that stand up to inspection outside in accounting the expenses (amount incurred) from collecting cord blood to preparing it.

In other words, rules need to be laid out about cord blood cost based on The Cost Accounting Standards that companies must follow, which is what is done in The Tentative Cord Blood Cost Accounting Guideline.

**Purpose**

Article 2: The Guideline complies with The Cost Accounting Standards established by the Ministry of Finance (Business Accounting Council, November 8, 1962). In addition to contributing to effective and systematic operations, cost management, and other management decisions, the purpose of The Guideline is to provide useful cost information for preparing financial statements. The Guideline applies the estimated and the actual cost to cost accounting system of cord blood.

Article 2 is costing purposes. There are some following important contents.

1. Relations with the cost accounting standards
2. The purpose of costing
3. Cost accounting system

First, Article 2 shows, cost accounting system of cord blood has actual cost (including the estimated cost). It adapts only the single cost accounting system.

While, company adopts actual cost accounting system and standard cost accounting system. Standard cost accounting system accounts cost with standard price. Standard cost refers to the cost measures consumption volume by standard multiplied by the price. Standard costs are derived by a scientific study. Many companies often adopt the standard cost accounting system.

But the cost of cord blood accounts actual cost instead of standard cost. This is a great feature because what processes is only cord blood. It is repeatedly processed in a single series of operations. Also, actual cost accounting system includes the estimated price. The estimated price is expected
over a future period of actual acquisition price. The price is similar to standard costs with the point of view on forecast.

The costing of cord blood is within the framework of actual cost accounting system as far as consumption volume by actual. Of course, there are difficulties setting the estimated price on the practice. It is the basic performances of the previous year.

There is *Tentative Cord Blood Cost Accounting Guideline* on the following next pages (Appendix).

**Main Bibliography**


Tentative Cord Blood Cost Accounting Guideline

Chapter 1: General Rules

General Rule


Purpose

Article 2 The Guideline complies with the Cost Accounting Standards established by the Ministry of Finance (Business Accounting Council, November 8, 1962). In addition to contributing to effective and systematic business operations, cost management, and other management decisions, the purpose of these Guideline is to provide useful cost information for preparing financial statements. The Guideline applies the estimated and the actual cost to cost accounting system of cord blood.

Related Guideline

Article 3
1 The cost accounting system must maintain an systematic relationship with the financial accounting system.
2 The cost on the Guideline shall be the cost described in Regulations 15 (1).

Definition of Cost

Article 4 The Guideline defines the cost as the economic value directly used by incurred in the processing of cord blood.

Non-cost Items

Article 5 The following items are not included in costing:
(1) Expenses unrelated to the processing of umbilical cord blood:
① Depreciation charges, administration expenses, taxes, and other expenses related to the following assets:
Investment assets
Unearned income on fixed assets
Facilities and equipment that have been out of commission for long periods of time
Other assets that are unrelated to processing.
② Expenses from related activities that are not directly related to processing.
③ Financial expenses such as interest expenses, discount expense, and guarantee charges.
④ Sales loss or appraisal loss from marketable securities.
⑤ Expenses resulting from unusual conditions or situations:
① Losses from abnormal spoilage, depletion, inventory asset shrinkage, etc.
② Losses from accidents.
③ Deposit for delay, breach of contract penalties, penalty charges, indemnity fees, litigation expenses.
④ Extraordinarily large retirement allowance payments.
⑤ Losses from the sale or disposal of fixed assets.

Method for Costing

Article 6
1 The method for costing, except whether otherwise defined, shall be actual total costing system.
2 The process for costing shall be accounted as item based costs, division based costs, product based costs, in that order.
3 Product based costs shall be accounted based on estimated cost.

Cost Accounting Period

Article 7 The cost accounting period shall be 1 month, starting from the first of each month to the last day of that month.
Chapter 2: Cost Accounting of Cord Blood

Section 1  Item Based Cost Accounting

Processing Cost Categories

Article 8  1 Processing costs are divided into incurred personnel expenses, material expenses, and operating expenses.
2 Personnel expenses are costs incurred in the use of labor.
3 Material expenses are costs incurred in the production of goods.
4 Operating expenses are costs other than personnel expenses and material expenses.

Types of Personnel Expenses, Material Expenses, and Operating Expenses

Article 9  The types of personnel expenses, material expenses, and operating expenses are described in Regulations, Attachment 1.

Costing of Personnel Expenses and Other Operating Expenses

Article 10 The amount of personnel and other operating expenses incurred shall be added to the processing costs in the applicable accounting period. However, personnel and other expenses stated in Attachment 1 shall be estimated at the beginning of 1 accounting year, and then divided by the number of months. This monthly amount shall be added to the processing cost in each cost accounting period. In this case, adjustments will be made at the end of the accounting year to account for discrepancies between the initial estimated expense and the actual incurred expense.

Costing of Material Expenses

Article 11  1 Material expenses shall be calculated based on purchase price.
2 When the same type of materials are purchased at different prices, the cost of materials used will be determined on first in first out basis.
3 The purchase price in paragraph 1 of this Article shall include the amount paid for materials and any additional associated expenses, such as payment fees, insurance fees, shipping, and cargo expenses. However, insignificant shipping fees and other expenses that would be difficult to add to the purchase price will be accounted for as business expenses.
4 As a general rule, the amount of materials used shall be calculated using the perpetual inventory method.

Section 2  Division Based Costing

Division Based Costing

Article 12  1 Division based costing will be accounted based on divisions determined by the Blood Programme Specific Accounting Section.
2 Division based costs are item based costs added together based on the division that generated the cost. Division based costs are procession based costs.

Expenses Based on Individual and Common Use

Article 13  1 Cost are divided into divisions and then added together. Thus, treating a cost as a individual expense or common expense depends on whether the cost is recognized as something that directly resulted from the applicable division.
2 Individual expenses are costs incurred directly from a division, and are treated as part of that division.
3 Common expenses are allocated among applicable divisions in accordance with the allocation standards established in Attachment 2.

Section 3  Product Based Costing

Simple Total Costing

Article 14  Cord blood costing shall be based and accounted as a simple total costing.

Estimated Costs

Article 15  1 Finished products and works in process shall be accounted for with estimated costs. The difference between the estimated cost and the actual cost shall be accounted for as a cost variance.
2 Estimated cost shall be the estimated unit price based on the actual processing costs from previous accounting years.
3 Estimated costs must be reviewed by the Japanese
Red Cross Society Blood Programme each accounting year before the start of the period in which the estimated cost will be used.

Section 4  Cost Variances

Cost Variance Accounting Method

Article 16  In each accounting year, all cost variances from the previous Article shall be accounted for as cord blood supply costs. However, when the cost variance exceeds 1% of that period’s total processing expenses, that amount shall be allocated between cord blood and cord blood supply costs.

Supplementary Provision
The Guideline will be effective starting April 1, 2013.

Attachment 1
Categories of expenses whose amount will be estimated at the beginning of the term and divided into monthly installments.

Attachment 2
Allocation standards for common expenses.

<table>
<thead>
<tr>
<th>Type of Expense</th>
<th>Cost Allocation Rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits and other employee related expenses</td>
<td>Divided by applicable number of employees</td>
</tr>
<tr>
<td>Rent, insurance, and other facility related expenses</td>
<td>Divided by applicable land area</td>
</tr>
<tr>
<td>Communication, entrustment, and other system related expenses</td>
<td>Divided by applicable number of computer terminals</td>
</tr>
</tbody>
</table>

In addition to the above, other common expenses can be allocated with notification from this organization.