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# The Experience of Human Milk Banking for 8 Years: Korean Perspective

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Human milk banks are a solution for mothers who cannot supply their own breast milk to their sick or hospitalized infants; premature infants, in particular, are unable to receive a full volume of breast milk for numerous reasons. As of December 2015, there was only one milk bank in a university hospital in Korea. We reviewed the basic characteristics of donors and recipients, and the amounts and contamination of breast milk donated at the Human Milk Bank in Kyung Hee University Hospital at Gangdong in Korea from 2008 to 2015. The donor pool consisted of 463 first-time donors and 452 repeat donors who made 1.724 donations. A total of 10,820 L of breast milk was collected, and 9,541.6 L were processed. Detectable bacteria grew in 12.6% after pasteurization and 52.5% had cytomegalovirus DNA before pasteurization in donated milk. There were 836 infant and 25 adult recipients; among new infant recipients, 48.5% were preterm; the groups received 8,009 and 165.7 L of donor milk, respectively. There was an increase in the percentage of preterm infants among new infant recipients in 2015 (93.1%) compared to 2008 (8.5%). Based on the number of premature infants in Korea, the number of potential recipients is not likely to diminish anytime soon, despite efforts to improve the breastfeeding rate. Sustainability and quality improvement of the milk bank need long-term financial support by health authorities and a nationwide network similar to blood banking will further contribute to the progress of milk banking.

Keywords: Milk, Human; Milk Banks; Infant, Premature; Korea

## **INTRODUCTION**

Breast milk has all the nutrients and protective immune components that infants need for healthy development, and seems to decrease the risk of allergic and infectious diseases, such as otitis media, and gastrointestinal tract and respiratory disease in infancy (1-4). Components of breast milk, such as immunoglobulins, lactoferrin, lysozyme, oligosaccharides, nucleotides, growth factors, enzymes, antioxidant factors, and cellular components, provide adequate host defense against infections, actively regulate the immune response, and modify intestinal bacterial colonization. Breastfeeding is the most suitable source of nutrition for preterm infants, and aids the cognitive development of premature babies; the psychological advantages have a positive effect on long-term prognosis (5-7). Thus, it is generally accepted that mother's milk is the best single source of nutrition for the first 6 months of life and is the optimal diet for healthy infants for the first 2 or more years of life (8-10).

However, sometimes a mother's own milk is unavailable or insufficient for numerous reasons despite the benefits of breastfeeding, and infants are often fed artificial formula. The World Health Organization (WHO), the United Nations International Children's Emergency Fund (UNICEF), and the American Academy of Pediatrics (AAP) state that the use of donor human milk should be the first alternative when maternal milk is not available, particularly for preterm neonates (11,12). A human milk bank (HMB) systematically collects, screens, processes, and dispenses excess human breast milk donated by healthy nursing mothers (13).

In 2010, we reported 2-year data for the HMB in the Kyung Hee University Hospital at Gangdong, from August 2007 to August 2009 (14). This is the second time that data about breast milk donors and recipients were collected as part of this survey. We report the operational status of the HMB for 8 years (from 2008 to 2015) in this hospital, to determine the direction of development and growth of the HMB.

### **MATERIALS AND METHODS**

The HMB in Kyung Hee University Hospital at Gangdong was opened in August 2007, and is a nonprofit milk bank that accepts donations of surplus milk from healthy breastfeeding women and dispenses donor human milk, primarily to premature and ill infants. This is the first established nationwide HMB in a Korean university hospital, and is still the only national level HMB in Korea. Our HMB follows the annually revised "Guide-

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lines of Human Milk Banking Association of North America (HMBANA)." Target users of our Guidelines are health care workers of the HMB, nurses and doctors of the neonatal intensive care unit (NICU), and administrators of the HMB. As part of the process of this HMB, donors are checked for eligibility. Safety checks are performed on collected breast milk from qualifying donors. At this time, unsuitable breast milk is discarded, and safe milk is pasteurized and provided to recipients. Table 1 shows the processes.

A donor is excluded if she has received an organ/tissue transplant within the prior 12 months or blood transfusion/blood products within the prior 4 months; regularly takes more than 2 ounces of alcohol or its equivalent, or 3 caffeinated drinks per day; uses illegal drugs, tobacco, or nicotine products; is taking radioactive or other drugs, has chemical or environmental exposures, or takes over-the-counter prescriptions or megadoses of vitamins known to be toxic to the neonate and are excreted in breast milk, and/or herbal products used as medication; has a positive blood test result for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), or syphilis; has a history of leukemia or lymphoma, or treatment for any other cancer within the prior 3 years; has a sexual partner with HBV, HIV, HCV, or sexually transmitted infections, or if either partner has high-risk behavior for contracting these in the prior 12 months; has had tattoos with non-sterile needles or dyes used by multiple persons at an unregulated site, permanent makeup applied with nonsterile needles, ear or other body parts pierced with other than single-use instruments in the prior 12 months; has mastitis or fungal infection of the nipple or areola, active herpes simplex or varicella zoster infections in the mammary or thoracic region; is a strict vegetarian who does not supplement their diet with vitamin B12; or has been incarcerated or has had a sexual partner who was incarcerated for more than 72 consecutive hours in the prior 12 months (11,15-17).

In this study, we reviewed the basic characteristics of donors (regional distribution, age, occupations, motivation and information on donation, donation time after delivery) and recipients (regional distribution, age), the number of donors and recipients, frequency of donation, amount of human milk for collection and processing, bacterial contamination rate of donor milk after pasteurization, donor milk containing cytomegalovirus (CMV) before pasteurization, indication for receiving donated milk, and additional issues to be resolved between January 2008 and December 2015. A standardized data form was used to collect information from the HMB.

After passing the exclusion criteria, all milk samples are transported to the milk bank, frozen, and maintained in freezers at -20°C for up to 6 months. Frozen milk samples are thawed in batches at 1°C-4°C and processed by the pasteurization standard for bottled human milk. Before processing, 3-4 samples from each individual donation are mixed to obtain homogenous fat contents and wide range of immune mechanisms, thereafter sent to the microbiology laboratory in the hospital to be screened for CMV using a real-time polymerase chain reaction (PCR) assay. After processing, pasteurized milk undergoes bacteriological testing to ensure the absence of detectable bacterial growth. In the hospital microbiology laboratory, each milk sample was inoculated onto blood agar plate and incubated aerobically at 36°C for 48 hours (11,15-18). All contaminated milk is discarded.

Table 1. Summary of the operation of a human milk bank in Kyung Hee University Hospital at Gangdong, Seoul, Korea

| A process from donation to distribution  |
|--|
| <ol> <li>Donation process         <ol> <li>Donation process</li> <li>Notice received of a mother's intention to donate milk (within 12 months after delivery)</li> <li>Report received regarding the donor's condition based on general health and laboratory data</li> <li>Examination of the donor's qualifications</li></ol></li></ol>  |
| 2. Door-to-door delivery service of frozen donated milk. Transportation from the donor's home to the human milk bank   |
| <ul> <li>3. Preparation at the human milk bank</li> <li>1) All required equipment</li> <li>2) Understanding of regulations for all aspects of the process and handling</li> </ul>  |
| <ul> <li>4. Donated milk processing <ol> <li>Discard unsuitable donated human milk: more than three months old or damaged</li> <li>Suitable milk is kept frozen at -20°C</li> <li>Thawing (at 1°C-4°C for 3 days) and pooling</li> <li>Mixed breast milk is distributed in sterilized glass containers and pasteurized at 62.5°C for 30 minutes</li> <li>Safety is proven, the milk is kept frozen at -20°C until use</li> </ol></li></ul> |
| <ul><li>5. Accepting applications by recipients</li><li>1) Verifying the indication</li><li>2) Examination and selection of appropriate recipients</li></ul>   |
| <ul> <li>6. Distribution of processed donor milk</li> <li>- Shipping the processed frozen donor milk: from human milk bank to hospitals and individual recipients at home</li> </ul>   |

#### **Ethics statement**

Data collection was approved by the institutional review board (IRB) of Kyung Hee University Hospital at Gangdong. The informed consent requirements for this retrospective review were waived by the IRB (Approved number, KHNMC NON2016-002).

## RESULTS

Number of human milk donors and frequency of donation Table 2 shows the number of human milk donors and frequency of donation. During the 8 years of the study period, the number of new donors was 64 in 2008, 40 in 2009, 67 in 2010, 50 in 2011, 49 in 2012, 40 in 2013, 86 in 2014, and 67 in 2015. There were a total of 916 donors. In the distribution of donors by year, there were 74 in 2008, 73 in 2009, 104 in 2010, 134 in 2011, 112 in 2012, 106 in 2013, 160 in 2014, and 153 in 2015. Although there had not been a marked increase or decrease for 8 years, the total number of donors showed a tendency to increase.

The number of donations per year were 179 in 2008, 132 in

Table 2. Number of human milk donors and frequency of donation

| Doriod  |     | No. of donors |       | Frequency of donation |
|---------|-----|---------------|-------|-----------------------|
| renou - | New | Existing      | Total | Total (per donor)     |
| 2008    | 65  | 9             | 74    | 179 (2.4)             |
| 2009    | 40  | 33            | 73    | 132 (1.8)             |
| 2010    | 67  | 37            | 104   | 208 (2.0)             |
| 2011    | 50  | 84            | 134   | 262 (2.0)             |
| 2012    | 49  | 63            | 112   | 162 (1.4)             |
| 2013    | 40  | 66            | 106   | 194 (1.8)             |
| 2014    | 86  | 74            | 160   | 302 (1.9)             |
| 2015    | 67  | 86            | 153   | 285 (1.9)             |
| Total   | 463 | 452           | 916   | 1,724 (1.9)           |

**Table 3.** Characteristics of new donors (n = 463)

| Parameters  | No.                                   | %   |
|---|---------------------------------------|---|
| Regional distribution<br>Seoul<br>Gyeonggi-do & Incheon<br>Other areas  | 172<br>158<br>133                     | 37.2<br>34.1<br>28.7                            |
| Age, yr<br>20-29<br>30-39<br>40-45  | 130<br>323<br>10                      | 28.0<br>69.8<br>2.2                             |
| Occupations<br>Housewife<br>Office worker<br>Teacher/public servant<br>Medical personnel<br>Business<br>Student<br>Others | 288<br>83<br>38<br>29<br>9<br>2<br>14 | 62.3<br>17.9<br>8.2<br>6.3<br>1.9<br>0.4<br>3.0 |
| Motivation & information about donation<br>Online<br>Recommendation of acquaintances<br>Television & magazine<br>Others   | 352<br>43<br>31<br>37                 | 76<br>9.3<br>6.7<br>8                           |

2009, 208 in 2010, 262 in 2011, 162 in 2012, 194 in 2013, 302 in 2014, and 285 in 2015, for a total of 1,724 donations. The average number of donations per donor was greatest at 2.4 in 2008 and lowest at 1.4 in 2012, with an average overall number of donation per donor of 1.9. Although the frequency of donation increased up to 302 in 2014, the number of donations per donor showed no significant difference by year.

#### Characteristics of breast milk donors

Analysis of the 463 breast milk donors newly registering each year revealed the following (Table 3). In terms of geographical distribution, donors residing in Seoul accounted for the majority, at 37.2%, followed by those residing in the Gyeonggi and Incheon area, who accounted for 34.1% of the total. When combined, donors from the 2 areas accounted for 71.3% of the total. with 28.7% from other areas. Age distribution of new donors ranged from 20 to 45 years, with those aged 30-39 years accounting for the majority, at 69.8%. In terms of occupation, stay-athome mothers accounted for the majority at 62.3%, followed by office workers at 17.9%, educators and government workers at 8.2%, healthcare professionals at 6.3%, and students at 0.4%. As for donor sources of information and motivation, the internet accounted for the majority at 76%, followed by recommendation of friends at 9.3%, TV and magazines at 6.7%, and others at 8%, suggesting that donors typically turn to on-line resources.

Donation was accepted from new mothers for up to 12 months postpartum. Donors typically started to donate breast milk 1-3 months postpartum, accounting for over half of the total at 60.7%, followed by 4-6 months postpartum at 7.9%, 7-9 months postpartum at 6%, and 10-12 months postpartum at 1% (Fig. 1). One-time new donors accounted for 36% in 2012, 32.5% in 2013, and



Fig. 1. Amount of human donor milk by months after delivery (2009-2014).

Table 4. Percent distribution of new donors by number of times and donation period

| Year  | One time, % | Donation period,<br>mon | Donation period of multiple donors, mon |
|-------|-------------|-------------------------|---|
| 2012  | 36          | $2.0 \pm 2.4$           | 3.1 ± 2.3                               |
| 2013  | 32.5        | $2.0 \pm 2.3$           | $2.8 \pm 2.3$                           |
| 2014  | 53.5        | $1.3 \pm 2.1$           | $2.9 \pm 2.2$                           |
| Total | 50.6        | $1.7 \pm 2.2$           | $2.9 \pm 2.2$                           |

 Table 5. Amount of donor milk and frequency of bacterial contamination and cytomegalovirus detection

| Total collected Total p |                     | Total pasteurized | Frequency of bacterial contamination of donor milk |          |      | Frequency of CMV detection in donor milk |          |      |
|-------------------------|---------------------|-------------------|--|----------|------|--|----------|------|
| real                    | amount, L amount, L |                   | Negative   | Positive | %    | Negative                                 | Positive | %    |
| 2008                    | 1,009               | 942               | -  | -        | -    | -  | -        | -    |
| 2009                    | 1,746               | 1,540             | -  | -        | -    | -  | -        | -    |
| 2010                    | 1,667               | 1,581             | 148  | 17       | 10.3 | -  | -        | -    |
| 2011                    | 1,150               | 937               | 57   | 18       | 24   | -  | -        | -    |
| 2012                    | 883                 | 828.6             | 119  | 25       | 17.4 | 54                                       | 57       | 51.4 |
| 2013                    | 1,082               | 915               | 109  | 29       | 21   | 65                                       | 79       | 54.9 |
| 2014                    | 1,781               | 1,388             | 255  | 18       | 6.6  | 47                                       | 58       | 55.2 |
| 2015                    | 1,502               | 1,410             | 337  | 41       | 10.8 | 37                                       | 30       | 44.8 |
| Total                   | 10,820              | 9,541.6           | 1,025  | 148      | 12.6 | 203                                      | 224      | 52.5 |

CMV = cytomegalovirus.

Table 6. Cumulative number of recipients

| Year  | Infants | Adults | Total |
|-------|---------|--------|-------|
| 2008  | 68      | 0      | 68    |
| 2009  | 64      | 5      | 69    |
| 2010  | 113     | 9      | 122   |
| 2011  | 64      | 4      | 68    |
| 2012  | 94      | 5      | 99    |
| 2013  | 79      | 2      | 81    |
| 2014  | 124     | 0      | 124   |
| 2015  | 230     | 0      | 230   |
| Total | 836     | 25     | 861   |

53.5% in 2014, yielding an average of 50.6%. The average donation period among donors who made 2 or more donations was  $2.9 \pm 2.2$  months (Table 4).

# Characteristics of collected, processed, and discarded breast milk

The amounts of donated breast milk were as follows: 1,009 L in 2008, 1,746 L in 2009, 1,667 L in 2010, 1,150 L in 2011, and 883 L in 2012, which marked the lowest amount donated during the given period; 1,082 L was donated in 2013, followed by 1,781 L in 2014, which marked the highest amount during the given period, and 1,502 L in 2015. The amount of screened and processed breast milk was proportional to the amount of donated breast milk each year. A total of 10,820 L was collected during the 8 year period, of which 9,541.6 L was processed.

Bacterial growth was detected in 10.3% of donated breast milk in 2010, 24.0% in 2011, 17.4% in 2012, 21.0% in 2013, 6.6% in 2014, and 10.8% in 2015, indicating an average 12.6% detection rate. CMV tested positive with real time PCR in 51.4% in 2012, 54.9% in 2013, 55.2% in 2014, and 44.8% in 2015, indicating an average of 53.9%. CMV and bacterial detection tests were done before and after the processing in each of the mixed samples. So there is a difference in the number of tests (Table 5). The purpose of the CMV detection test is to prevent potential CMV infection in extremely low birth weight infants by breast milk, only CMV negative breast milk is provided to extremely low birth weight infants. In general, human breast milk supplied to full-

Table 7. Total delivered amount and frequency by recipient

| Infants |                    | ants      | Ad                 | ults      | Total              |           |
|---------|--------------------|-----------|--------------------|-----------|--------------------|-----------|
| Year    | Total<br>amount, L | Frequency | Total<br>amount, L | Frequency | Total<br>amount, L | Frequency |
| 2008    | 717                | 155       | 0                  | 0         | 717                | 155       |
| 2009    | 1,298              | 200       | 54                 | 6         | 1,352              | 206       |
| 2010    | 1,131              | 170       | 55.8               | 9         | 1,186.8            | 179       |
| 2011    | 482                | 88        | 22.3               | 4         | 504.3              | 92        |
| 2012    | 796                | 149       | 32.6               | 6         | 828.6              | 155       |
| 2013    | 894                | 124       | 1                  | 2         | 895                | 126       |
| 2014    | 1,294              | 203       | 0                  | 0         | 1,294              | 203       |
| 2015    | 1,397              | 428       | 0                  | 0         | 1,397              | 428       |
| Total   | 8,009              | 1,517     | 165.7              | 27        | 8,174.7            | 1,544     |

term neonates or infants is not required for the CMV detection test.

# The number of recipients, delivered amount, and frequency for the recipient

There were 68 recipients in 2008, 69 in 2009, 122 in 2010, 68 in 2011, 99 in 2012, 81 in 2013, 124 in 2014, and 230 in 2015; the number of recipients has risen sharply in the past 2 years. A total of 861 recipients consisting of 836 infants and 25 adults benefited from donated human milk. There were no adult recipients in 2008, 2014, and 2015, and all of the donations went to infant recipients (Table 6).

Of the 8,174.7 L of donor milk supplied during the 8 year period, 8,009 L (98%) were distributed to infants and 165.7 L (2%) to adults. There was no significant trend from year to year in terms of the amount distributed. The least amount distributed at 504.3 L was in 2011, while 2015 saw the highest amount distributed at 1,397 L. A total of 1,544 distributions were made during the 8-year period, with approximately 5.3 L of donor milk per distribution. The lowest number of distributions was seen in 2011 at 92, while the highest number was in 2015, at 428. The number of breast milk distributions as well as the amount distributed were the highest in 2015. Since 2011, both the number of recipients and the amounts distributed have been increasing (Table 7).



Fig. 2. Reasons for receiving donated human milk by infants.

| Table 8. | Characteristics | of new | recipients | (n = 462) |  |
|----------|-----------------|--------|------------|-----------|--|
|----------|-----------------|--------|------------|-----------|--|

| Parameters            | No.  | %    |
|-----------------------|------|------|
| Regional distribution |      |      |
| Seoul                 | 167  | 36.2 |
| Gyeonggi-do & Incheon | 208  | 45.0 |
| Other areas           | 87   | 18.8 |
| Age                   |      |      |
| Infants, mon          | 0.05 |      |
| 0-3                   | 295  | 63.9 |
| 4-6                   | 66   | 14.3 |
| 7-9                   | 35   | 7.6  |
| 10-12                 | 23   | 5.0  |
| 12-24                 | 3    | 0.6  |
| > 24                  | 11   | 2.4  |
| Adults ( > 20 yr)     | 29   | 6.2  |

#### **Characteristics of recipients**

A total 36.2% of the recipients resided in Seoul, 45% in the Gyeonggi-Incheon area, and 18.8% in other areas. Although Seoul and Gyeonggi-Incheon areas accounted for 81.2% of the total, it is clear that the breast milk bank is operating at a national level. Of newly registered recipients, 433 were infants at 93.7%, and 29 were adults at 6.3% of the total. Within the group of infant recipients, those aged 0-3 months accounted for 63.9%, 4-6 months for 14.3%, 7-9 months for 7.6%, 10-12 months for 5%, 12-24 months for 0.6%, and 24 months and older for 2.4% of the total. Donor milk was distributed to a relatively wide range of infants in terms of age, and showed a decreasing trend as the infant's age increased (Table 8).

The reasons for requiring donated breast milk among infant recipients included "preterm baby" at 48.5%, followed by "mother's diminished breast milk production" at 17.5%, "baby's rejection of formula/formula allergies" at 15%, "reasons related to mother's health" at 8.8%, atopic dermatitis at 8.8%, and environmental causes including adoption at 1.4%. When the reasons were analyzed by year, it was found that "mother's diminished breast milk production" was the most common reason for requiring donated breast milk in 2008 and 2009, while "formula allergies" was the most common reason in 2010. In 2011, "baby's rejection of formula/formula allergies" and "mother's diminished breast milk production" were the most common reasons for requiring donated breast milk. From 2012 to 2015, "preterm baby" was the most common cause of breast milk distribution, with a growing proportion of premature infants among the recipients. In 2015, premature infants accounted for the vast majority at 93.1% (Fig. 2).

#### DISCUSSION

The benefits of breast milk are widely known. The Baby Friendly Hospital Initiative (BFHI) by WHO/UNICEF recommends that newborns be breastfed within 30 minutes of birth, and exclusively breastfed until 6 months of age. Breast milk is a superior nutritional source that contains high levels of important immunological components that protect against infections. In addition, breastfeeding promotes emotional and motor development in babies (19,20). Breastfeeding also reduces the risk of necrotizing enterocolitis, sepsis, retinopathy of prematurity, and hospital readmission of preterm infants after discharge (12,21).

Unfortunately, there are circumstances where mothers are not able to breastfeed their babies for a number of reasons despite the various benefits. Commercial infant formula is a common replacement for breast milk in these instances. However, donor breast milk can be an excellent alternative to formula. The role of an HMB is to ensure that this alternate route to breastfeeding is safe and efficient. On-line breast milk transactions have recently increased as a result of internet promotion and increasing awareness of the benefits of breast milk. However, such transactions include the risks of infection and spoilage (22). Therefore, donating and receiving breast milk through an

#### HMB is essential.

The first HMB was founded in 1909 in Vienna, Austria. The USA, Germany, and the UK followed shortly thereafter. However, early HMBs were not equipped to provide systematic and sanitary processing of breast milk. In 1985, the modern Human Milk Banking Association of North America (HMBANA) was founded in an effort to establish necessary standards for safe and efficient milk banking. Upon the establishment of standardized guidelines, human milk banking took off full force (14,16). In the mid-1980s, with the advent of AIDS (Acquired Immune Deficiency Syndrome), stringent blood testing, and donor screening, many HMBs closed. Since the 1990s, research on the safety of breast milk and breastfeeding has prompted active plans to establish HMBs in many developed countries around the world (23). In many countries, HMBs have been incorporated into child health policy and are protected, promoted, and supported as an extension of national breastfeeding policies (13,24-26). Currently, there are 24 established and 5 developing HMBs in North America and 210 active and 17 planned HMBs in Europe. Brazil is an international leader. with 217 HMBs and 162 collection centers distributed throughout the country in 2012 (27-29).

The first HMB in Korea was founded in 2007 by the Children and Maternal Health Center of Gangdong Kyung Hee University. Other HMBs currently in operation in Korea include one run by the Seoul Injeong Hospital, Incheon's "Shared Love" milk bank (the only milk bank run by an Oriental medicine clinic), and one run by the obstetric department of Jeonbuk Iksan Jeil hospital, all of which operate in cooperation with the Korea Breastfeeding Association. The HMB process in Gangdong Kyung Hee University is as follows. Collected breast milk is processed in a designated area by staff members wearing face masks, aprons, and sanitary gowns. The milk is kept frozen at -20°C. Breast milk collected from a minimum of 3 individuals is thawed at 1°C-4°C for 3 days. Thawed breast milk subsequently goes through a process of mixing and pooling which ensures homogenous nutritional composition and immunological properties. Mixed breast milk is distributed in sterilized glass containers and pasteurized at 62.5°C for 30 minutes. The pasteurization process is designed to eliminate the risks of infection including HIV and CMV (30). Pasteurized breast milk is then rapidly cooled in an ice bath for 30 minutes to ensure an effective vacuum seal. Samples of processed breast milk are selected for microbiological examination including bacteria. If safety is proven, the milk is kept frozen at -20°C until use. Each container is labeled with an expiration date 6 months from the date of bottling. Recipients apply for the program via telephone calls. The first priority is given to premature infants in clinics, followed by infants in the NICU, infants with formula allergies, adopted infants or infants whose birth mothers passed away, and adults who are receiving cancer treatment.

Following the above described process, a total of 916 donors participated in the milk banking program run by Gangdong Kyung Hee University during the 8-year period between 2008 and 2015, with a total of 1,724 donations and an average of 1.9 donations per donor. The total amount of donated breast milk during the 8-year period was 10,820 L, 9,541.6 L of which was processed. In the beginning, the number of new donors and the number of donations increased each year, which is attributed to active promotion efforts via websites, internet cafes, media coverage, and various expos. The increasing trend in donors and donations between 2008 and 2011 started to decline afterwards, and peaked again in 2015, suggesting that human milk banking did not achieve steady quantitative growth. Considering the fact that 76% of donors are inspired by on-line sources, greater promotional efforts will have to be invested in electronic sources including the internet. In addition, promoting milk banking and improving accessibility through various events designed to attract pregnant women and breastfeeding mothers in their 20s and 30s appears to be critical for continued growth of milk banking. In terms of donor occupations, although stav-at-home mothers accounted for the majority at 62.3%, working mothers and students accounted for 37.7% of the total, suggesting that their participation is important. As for geographical distribution of donors, Seoul, Gyeonggi-do, and Incheon areas accounted for a significant majority at 71.3%. However, other areas supplied 28.7% of the total, indicating nationwide participation.

Bacterial growth was positive in 12.6% of processed breast milk. HMBs in many other countries perform bacteriological screening both before and after processing (18,31). However, we perform screening only after processing as a way to reduce cost and deal with a shortage of healthcare professionals. Although precise statistics have not been calculated, most cases involved Bacillus species. Spore-forming Bacillus species are known to survive routine Holder pasteurization, but unlike cow's milk, this is a rare contaminant of human breast milk and is detectable by surveillance cultures performed before and after pasteurization (32,33). CMV tested positive in 52.5% of breast milk before being processed. CMV disease caused by postnatally acquired infection is uncommon in full-term infants, presumably because of protection from passive transfer of maternal antibodies that occurs mostly in the third trimester, and the infant's more mature immune system (34,35). However, infants born at less than 32 completed weeks of gestational age or very low birth weight (VLBW) infants (< 1,500 g) may be at higher risk of developing symptomatic postnatal CMV disease, characterized by hepatopathy, thrombocytopenia, neutropenia, petechiae, respiratory distress syndrome, and a sepsis-like syndrome (36). Therefore, our HMB only provides breast milk tested negative for CMV to infants born at less than 32 completed weeks of gestational age, or to VLBW infants until 34 completed weeks of corrected age.

**JKMS** 

During the 8-year period, a total of 861 recipients benefited from donated human milk, including 836 infants (97.1%) and 25 adults (2.9%). Breast milk was provided to a relatively wide range of age groups, and 63.9% was distributed to infants aged 0-3 months. A total of 8,174.7 L of donor milk was supplied during the 8-year period. A total of 1,544 distributions were made, for an average of 5.3 L per person. The most common reason for receiving donated breast milk was a premature baby, which appears to be growing in proportion in recent years. Although the majority of the recipients were preterm infants, donor milk was also being ordered for babies and children for a variety of other reasons, including adoption, atopic dermatitis, baby's refusal of formula, milk allergy, decreased amount of mother's breast milk, and mother receiving chemotherapy for cancer or underlying diseases. A notable trend in recent years is that premature babies made up a significant proportion of recipients. The survival rate in premature babies born with respiratory issues has increased due to advances in respiratory treatment, but necrotizing enterocolitis (NEC) is still a major factor in neonatal morbidity. According to guidelines, early trophic feeding using breast milk helps reduce the risk of NEC (12,37). However, most donor breast milk is provided by women who have delivered at term and they donate their milk in later lactation. Several months after delivery, this milk from mothers of term infants is low in protein, fat, and many bioactive molecules compared to preterm milk provided in the first few weeks after delivery and pasteurization has detrimental effects on the bioactive components of human milk and results in significant decreases in sIgA, lactoferrin, lysozyme, insulin-like growth factors, hepatocyte growth factor, water-soluble vitamins, bile saltstimulated lipase, lipoprotein lipase, and anti-oxidant activity (6,38). Pasteurized donor breast milk is therefore likely to be less beneficial than mother's own unpasteurised milk, and the maximum effort should always be put in supporting and promoting breastfeeding mother's own milk prior to donor breast milk being used. However, because preterm infants stay in the NICU and spend long hours separated from their mothers, breastfeeding becomes more challenging than breastfeeding full-term infants. Therefore, breast milk whose safety has been verified by HMBs is especially needed for preterm infants, and clinics with a NICU should consider having an HMB on site (39).

Our HMB provides a free shipping unit to mother's home to collect all the milk who are interested in donating and accept frozen breast milk expressed prior to the screening as well as long as it has not been frozen for over 3 months using post office home-delivery. The post office's great assets are the doorto-door delivery system and speedy delivery service of a day. Quite a few area are inaccessible, however, we cannot accept their breast milk even though there are mothers who want to donate.

In 2015, there were 13 hospitals in the Seoul/Gyeonggi area

receiving donor breast milk from the HMB in the Kyung Hee University Hospital at Gangdong. Breast milk demand for bank milk exceeds expectations yearly especially for preterm babies, and donations even have exceeded our processing capacity. Current fund for operation of our HMB was mostly from the Kyung Hee University Hospital at Gangdong. We cannot expand HMB space or buy refrigerators anymore. Maybe it is time to concern how ethically to allocate this scarce resource.

Fees generated from our banked milk are \$2.80/100 mL for babies in outside hospitals and outpatients, and free for babies in NICU at Kyung Hee University Hospital at Gangdong. The processing fee of each month in the HMB is around \$1,730 except personnel expenses. We want to obtain better quality control on operation and less loss of milk nutrients to benefit all infants and aim to analyze the nutritional components of the donor milk, and distributed to preterm babies at different stages individually. However, a single institution's effort is not sufficient for quantitative and qualitative growth in milk banking. Sustainability and quality improvement of the milk bank need long-term financial support by health authorities.

There is a growing body of evidence and expert opinion to support the use of donor human milk for hospitalized preterm or sick infants. A great deal of human resources, equipment, costs associated with testing and logistics are required to operate HMBs, which is a factor impeding proliferation of new milk banks. Meeting the growing demand for donor human milk will require leadership organizations and health care professionals at the national and local levels to develop strategic initiatives for new milk banks as well as increasing the number of breastfeeding mothers who donate milk. However, there are no governmental models that incorporate the need for donor milk into comprehensive breastfeeding strategies for improving maternal and child health outcomes. Thus, local governmentallevel funding is necessary. Additionally, establishing a nationwide network similar to blood banking will further contribute to the progress of milk banking. It is expected that Gangdong Kyung Hee University's milk bank will serve as the hub of progress based on the past 9 years of experience as the nation's leader in milk banking.

### DISCLOSURE

The authors have no potential conflicts of interest to disclose.

### **AUTHOR CONTRIBUTION**

Research conception & design: Jang HL, Cho JY, Kim MJ, Kim EJ. Choi YS, Bae CW, Chung SH. Data acquisition: Park EY, Park SA, Kim IY. Data analysis and interpretation: Chung SH. Drafting of the manuscript: Jang HL. Critical revision of the manuscript: Chung SH. Approval of final manuscript: all authors.

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#### REFERENCES

- Verhasselt V, Milcent V, Cazareth J, Kanda A, Fleury S, Dombrowicz D, Glaichenhaus N, Julia V. Breast milk-mediated transfer of an antigen induces tolerance and protection from allergic asthma. *Nat Med* 2008; 14: 170-5.
- 2. Ballard O, Morrow AL. Human milk composition: nutrients and bioactive factors. *Pediatr Clin North Am* 2013; 60: 49-74.
- Field CJ. The immunological components of human milk and their effect on immune development in infants. J Nutr 2005; 135: 1-4.
- Abrahams SW, Labbok MH. Breastfeeding and otitis media: a review of recent evidence. *Curr Allergy Asthma Rep* 2011; 11: 508-12.
- 5. Bertino E, Giuliani F, Occhi L, Coscia A, Tonetto P, Marchino F, Fabris C. Benefits of donor human milk for preterm infants: current evidence. *Early Hum Dev* 2009; 85: S9-10.
- 6. Underwood MA. Human milk for the premature infant. *Pediatr Clin North Am* 2013; 60: 189-207.
- 7. Whitelaw A, Heisterkamp G, Sleath K, Acolet D, Richards M. Skin to skin contact for very low birthweight infants and their mothers. *Arch Dis Child* 1988; 63: 1377-81.
- World Health Organization. Breastfeeding [Internet]. Available at http:// www.who.int/topics/breastfeeding/en [accessed on 10 March 2016].
- 9. World Health Organization. Exclusive breastfeeding [Internet]. Available at http://www.who.int/nutrition/topics/exclusive\_breastfeeding/en [accessed on 10 March 2016].
- United Nations International Children's Emergency Fund. Breastfeeding: recommendations for optimal breastfeeding [Internet]. Available at http: //www.unicef.org/nutrition/index\_24824.html [updated on 29 July 2015; accessed on 10 March 2016].
- Infant and Young Child Feeding Chapter, Indian Academy of Pediatric, Bharadva K, Tiwari S, Mishra S, Mukhopadhyay K, Yadav B, Agarwal RK, Kumar V. Human milk banking guidelines. *Indian Pediatr* 2014; 51: 469-74.
- Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics* 2012; 129: e827-41.
- Brownell EA, Lussier MM, Herson VC, Hagadorn JI, Marinelli KA. Donor human milk bank data collection in North America: an assessment of current status and future needs. *J Hum Lact* 2014; 30: 47-53.
- 14. Song KH, Lee YM, Chang JY, Park EY, Park SA, Cho NK, Bae CW. A report on operating a nationwide human milk bank in Korea. *Korean J Pediatr* 2010; 53: 488-94.

- 15. Landers S, Hartmann BT. Donor human milk banking and the emergence of milk sharing. *Pediatr Clin North Am* 2013; 60: 247-60.
- Updegrove K. Nonprofit human milk banking in the United States. J Midwifery Womens Health 2013; 58: 502-8.
- 17. Human Milk Banking Association of North America. Guidelines for the Establishment and Operation of a Donor Human Milk Bank. 6th ed. Forth Worth, TX: Human Milk Bank Association of North America, 2009.
- Landers S, Updegrove K. Bacteriological screening of donor human milk before and after holder pasteurization. *Breastfeed Med* 2010; 5: 117-21.
- World Health Organization; United Nations International Children's Emergency Fund. Baby-friendly Hospital Initiative: Revised, Updated and Expanded for Integrated Care. Geneva: World Health Organization, 2009.
- 20. Praveen P, Jordan F, Priami C, Morine MJ. The role of breast-feeding in infant immune system: a systems perspective on the intestinal microbiome. *Microbiome* 2015; 3: 41.
- Delfosse NM, Ward L, Lagomarcino AJ, Auer C, Smith C, Meinzen-Derr J, Valentine C, Schibler KR, Morrow AL. Donor human milk largely replaces formula-feeding of preterm infants in two urban hospitals. *J Perinatol* 2013; 33: 446-51.
- 22. St-Onge M, Chaudhry S, Koren G. Donated breast milk stored in banks versus breast milk purchased online. *Can Fam Physician* 2015; 61: 143-6.
- Mizuno K, Sakurai M, Itabashi K. Necessity of human milk banking in Japan: questionnaire survey of neonatologists. *Pediatr Int* 2015; 57: 639-44.
- 24. Arnold LD. Global health policies that support the use of banked donor human milk: a human rights issue. *Int Breastfeed J* 2006; 1: 26.
- Grøvslien AH, Grønn M. Donor milk banking and breastfeeding in Norway. J Hum Lact 2009; 25: 206-10.
- 26. Arnold LD. Donor milk banking in Scandinavia. J Hum Lact 1999; 15: 55-9.
- Human Milk Banking Association of North America. Locations [Internet]. Available at https://www.hmbana.org/locations [accessed on March 2016].
- European Milk Bank Association. Human milk banks [Internet]. Available at http://www.europeanmilkbanking.com/ [accessed on 10 March 2016].
- 29. Brasil Ministério da Saúde, Rede Brasileira de bancos de leite humano. Bancos de leite humano localização e relatório [Network of human milk banks] [Internet]. Available at http://www.fiocruz.br/redeblh/cgi/cgilua. exe/sys/start.htm?tpl=home [accessed on 10 March 2016].
- Corpeleijn WE, Vermeulen MJ, van Vliet I, Kruger C, van Goudoever JB. Human milk banking-facts and issues to resolve. *Nutrients* 2010; 2: 762-9.
- Hartmann BT, Pang WW, Keil AD, Hartmann PE, Simmer K; Australian Neonatal Clinical Care Unit. Best practice guidelines for the operation of a donor human milk bank in an Australian NICU. *Early Hum Dev* 2007; 83: 667-73.
- 32. Crielly EM, Logan NA, Anderton A. Studies on the Bacillus flora of milk and milk products. *J Appl Bacteriol* 1994; 77: 256-63.
- Kim J, Unger S. Human milk banking. *Paediatr Child Health* 2010; 15: 595-602.
- 34. Mussi-Pinhata MM, Pinto PC, Yamamoto AY, Berencsi K, de Souza CB, Andrea M, Duarte G, Jorge SM. Placental transfer of naturally acquired, maternal cytomegalovirus antibodies in term and preterm neonates. J Med Virol 2003; 69: 232-9.
- Dworsky M, Yow M, Stagno S, Pass RF, Alford C. Cytomegalovirus infection of breast milk and transmission in infancy. *Pediatrics* 1983; 72: 295-9.
- Vochem M, Hamprecht K, Jahn G, Speer CP. Transmission of cytomegalovirus to preterm infants through breast milk. *Pediatr Infect Dis J* 1998;

17:53-8.

- Choi YY. Necrotizing enterocolitis in newborns: update in pathophysiology and newly emerging therapeutic strategies. *Korean J Pediatr* 2014; 57: 505-13.
- 38. Ewaschuk JB, Unger S, Harvey S, O'Connor DL, Field CJ. Effect of pasteur-

ization on immune components of milk: implications for feeding preterm infants. *Appl Physiol Nutr Metab* 2011; 36: 175-82.

39. Marinelli KA, Lussier MM, Brownell E, Herson VC, Hagadorn JI. The effect of a donor milk policy on the diet of very low birth weight infants. *J Hum Lact* 2014; 30: 310-6.