

# Eight-year Operation Status and Data Analysis of the First Human Milk Bank in East China

**Xiaoshan Hu**

Nanjing Maternal and Child Health Hospital <https://orcid.org/0000-0001-5131-0816>

**Xue Chu**

Nanjing Maternity and Child Health Care Hospital

**Jun Zhang**

Nanjing Maternity and Child Health Care Hospital

**Feng Liu**

Nanjing Maternity and Child Health Care Hospital

**Xiaohui Chen**

Nanjing Maternity and Child Health Care Hospital

**Zhangbin Yu**

Nanjing Maternity and Child Health Care Hospital

**Shuping Han** (✉ [shupinghan@njmu.edu.cn](mailto:shupinghan@njmu.edu.cn))

Nanjing Maternity and Child Health Care Hospital

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## Research

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# Abstract

## Objectives

To analyze the operation status and data over the last 8 years of operation of the first human milk bank (HMB) in East China.

## Methods

Data related to the costs, donors, donation, pasteurization, and recipients were extracted from the web-based electronic monitoring system of the HMB for the period August 1, 2013 to July 31, 2021.

## Results

Over the 8 years of operation, 1,555 qualified donors donated 7,396.5 L of qualified milk at a cost of ¥1.94 million, with the average cost per liter of donor human milk being ¥262.3. The donors were between 25 and 30 years of age, and the majority (80.1%) were primipara. All the donated milk was pasteurized and subjected to bacteriological tests before and after pasteurization: 95.4% passed the pre-pasteurization tests, and 96.3% passed the post-pasteurization tests. A total of 9,207 newborns received 5,775.2 L of pasteurized donor milk. The main reason for the prescription of donor human milk was preterm birth. As a result of continuous quality improvements, January 2016 witnessed a significant increase in the volume of qualified DHM and the number of qualified donors. However, in 2020, as a result of the restrictions related to the COVID-19 pandemic, the volume of qualified DHM and the number of qualified donors decreased.

## Conclusions

Over its 8 years of operation, our HMB has made steady quality improvements in its screening and information processes. Continuous quality improvement is an ongoing need, along with recruiting more qualified donors and collecting donor human milk for vulnerable newborns.

# Introduction

Breast milk is the ideal source of nutrition for newborns within 6 months after birth<sup>[1]</sup>. Compared to formula, both breastfeeding and human milk have immense advantages, as they are associated with reduced rates of chronic lung disease, necrotizing enterocolitis, feeding intolerance, nosocomial infection, retinopathy of prematurity, and mortality in premature infants<sup>[2-4]</sup>. Therefore, donor human milk (DHM) is preferred to formula when maternal milk is absent or insufficient, as recommended by the World Health Organization<sup>[5]</sup>. Although the properties of DHM are affected by the processes of collecting, processing, and storing, it is still better than formula in terms of nutritional composition and biological value<sup>[6-7]</sup>.

Human milk banks (HMBs) are essential facilities for the selection, collection, testing, transportation, storage, and distribution of DHM for special medical needs. The first HMB was established in 1909 in Vienna, and since then HMBs have been set up in Europe and in the United States and have been in operation for more than 100 years<sup>[8]</sup>. The first HMB in China was opened in March 2013 in Guangzhou<sup>[9]</sup>, and as of 2019, China had 19 HMBs<sup>[10]</sup>. Our HMB is the first and largest HMB in East China. It was founded in August 2013 according to the standards and guidelines of the Human Milk Banking Association of North America, and has been in operation for 8 years. Over its 8 years of operation, a total of 7,396.5 L of qualified DHM has been collected, and 9,207 newborns have received DHM from our bank. We have made continuous quality improvements over these 8 years, and the purpose of this study is to describe these changes and the operation status of our HMB over the 8 years, and provide some recommendations to other HMBs operating in China.

# Materials And Methods

## 1. Data resources and research variables

Data from August 2013 to July 2021 were extracted from the computerized information management system of our HMB. The extracted donor data included age, education, residence address, occupation, number of children, number of donations, etc. Additionally, the results of bacteriological tests done before and after pasteurization were obtained. The extracted recipient data included gestational age, birth weight, mode of childbirth, number of days that DHM was used, etc.

## 2. Current donation process

Donors are eligible only if they pass the health screening, serological test (including HBV, HCV, HIV, syphilis and CMV), and bacteriological test (both pre- and post-pasteurization tests) at the time of the first donation. All eligible donors receive on-site guidance by professionals at the time of their first donation. Before breast milk collection, the donors are requested to wash their hands under strict instructions and clean their breasts with antiseptic wipes, especially around the nipple and areola. An electric milk absorption pump is used, and all accessories are cleaned and disinfected before and after use. The collected breast milk is placed in a dedicated storage container and placed in a 4°C refrigerator, and all the relevant information is recorded. All the donor milk is mixed and pasteurized (by continuous disinfection at 62.5°C for 30 min) within 24 h after collection and then stored in a special -20°C refrigerator for no more than 3 months (Fig. 1). Due to the restrictions imposed by COVID-19, our HMB now only accepts on-site milk donation, and does not accept milk donations collected at home.

### **3. Ethics**

Our HMB was approved by our hospital's ethics committee before it was established. Potential donors are provided with the necessary information and sign the consent form before their first donation. Additionally, a medical informed consent form is signed by the parents of the recipients before DHM is provided.

## **Results**

### **1. Infrastructures and cost analysis**

Our HMB is equipped with an independent milk collection room, a hospital-level milk pump, a pasteurizer (temperature-controlled water bath), human milk storage containers, medical refrigerators (including a custom-made ordinary refrigerator and special ultra-low temperature refrigerator), computers with a supporting information management system, etc. The guidelines for organizational management; infrastructure; donor screening; and the collection, processing, storage, and provision of donated breast milk are in accordance with The Human Milk Banking Association of North America.

The total cost for 8 years was ¥1.94 million for 7,396.5 L of qualified DHM. The average cost per liter of DHM was ¥262.3. Before the establishment of the HMB, we received a donation of ¥1 million from a group of good Samaritans as start-up capital. The rest of the expenses were borne by our neonate department, which covered 80% of the cost, and the hospital, which covered 20% of the cost. The annual cost with its breakdown is shown in Table 1.

### **2. Characteristics of donors and donations**

Between August 1, 2013, and July 31, 2021, a total of 1,805 mothers were enrolled, but 250 did not pass the health screening or serological tests. The remaining 1,555 qualified donors were mostly between 25 and 30 years of age (55.5%): 62.6% had a bachelor's degree, 61.2% had given birth by vaginal delivery, 66.7% had had term births, and 80.1% were primipara (Table 2). Further, 46.2% of donors had donated milk more than 10 times (Table 2).

The total number of donations in 8 years was 19,089, and the annual maximum number of donors was 195 (in 2014) (Fig. 2A). In 2013, the number of qualified donors was 91 and the volume of qualified DHM was 102.2 L. As a result of continuous quality improvements, January 2016<sup>[11]</sup> witnessed a significant increase in both the volume of qualified DHM and the number of qualified donors. In 2020, the number of patients at our NICU decreased due to the COVID-19 pandemic, and the volume of qualified DHM and the number of qualified donors consequentially decreased (Fig. 2B and 2C).

### **3. Processing of DHM**

Prior to January 2016, donors who passed the health screening, serological test, and bacteriological test (both pre- and post-pasteurization) at the time of the first donation were considered to be qualified and allowed to donate in the future without pre- or post-pasteurization bacteriological testing. After the continuous quality improvements, qualified donors' DHM was first pooled and then pasteurized. In the early stage of quality improvement, bacteriological testing was conducted before and after the pasteurization of each batch every day. It was subsequently found that our milk extraction process and pasteurization process were reliable if the batches passed most of the tests, and thereafter, bacteriological testing was conducted every 10 days and batches that failed the pre- and post-pasteurization bacteriological test were discarded. On average, 95.4% of the batches passed the pre-pasteurization tests, and 96.3% passed the post-pasteurization tests (Fig. 3).

### **4. Recipient characteristics**

Over the 8-year study period, a total of 5,775.2 L of DHM was supplied to 9,207 infants (Fig. 2C), and the maximum individual volume was 13.7 L. Most of the recipients were preterm (83.3%), and 81.7% were single birth. In 64.4% of the recipients, the birth weight was between 1,500 g and 2,500 g, and in 41.7%, gestational age was between 34 wk to 37 wk. Further, 94.3% of them received DHM for less than 15 days, and the average of duration for receiving DHM was 4.5 days (Table 3).

## Discussion

This study describes the operations of our HMB and analyzes the data gathered over the last 8 years of its existence. Over the 8-year period, the total expenditure of the HMB was 1.94 million RMB, including employee salary, materials costs, test costs, etc., and both the donation and provision of DHM were free. The average cost per liter of qualified DHM was ¥262. In comparison, studies from the United States have calculated that 1 L of DHM costs approximately US \$150, and studies from Germany have reported a cost of €82.88 per liter of DHM<sup>[12-14]</sup>. The costs of our HMB are probably lower because most donors are not required to repeat the HBV,HCV,HIV and syphilis test when they donate within 6 months of their serological test, which is done during hospitalization at the time of delivery at our hospital. Despite this, the cost of providing DHM is much higher than the cost of formula and mother's own milk; additionally, breastfeeding could reduce the incidence of diseases, such as necrotizing enterocolitis and late onset sepsis, and save a lot of future medical costs<sup>[15]</sup>. Therefore, we also advocate and promote breastfeeding through various means at our HMB.

Over the 8-year period, a total of 250 mothers did not meet the criteria for donation because they did not pass the health screening or serological test. In 2015, 169 mothers did not qualify because donor milk was screened with the CMV-DNA test, which is positive in most Chinese mothers<sup>[16]</sup>. In fact, after pasteurization, the CMV-DNA test shows negative results, which means that the donor milk is not likely to cause neonatal infection<sup>[17]</sup>. Thus, after the continuous quality improvements that were initiated in January 2016, we only used the serum TORCH test for screening.

During the last 8 years of operation of the HMB, the number of qualified donors and the volume of qualified DHM first showed an increase and then a decrease. In 2016, we carried out quality improvement programs for the HMB that resulted in a considerable increase of the number of qualified donors and the volume of qualified DHM. Later, in 2018, we undertook breastfeeding quality improvement programs to highlight the importance of breastfeeding, and this resulted in an increase in the rate of feeding with mother's own milk and a decline in the number of qualified donors and the volume of qualified DHM. In 2020, the number of donors and the volume of DHM decreased significantly due to the restrictions imposed as a result of the COVID-19 pandemic.

Our donors were mainly aged between 25 and 30 years, and this is similar to the donor demographic of HMBs reported in Taiwan and Thailand<sup>[18-19]</sup>. Further, 66.7% of the donors in the present study delivered full-term infants. It is mainly because the mothers of preterm infants have a reduction in postpartum lactation due to physical reasons<sup>[20]</sup>. In the present study, 61.2% of donors gave birth by vaginal delivery. This percentage is different from that reported in Thailand<sup>[17]</sup>, but is similar to a previous report in mainland China<sup>[7]</sup>. Further, 46.2% of the donors in this study donated more than 10 times, which is higher than the percentage reported in mainland China and indicates that we have a higher average number of donations than other domestic HMBs. This is probably attributable to the efforts of our staff in providing correct information and following up with donors. Additionally, 62.6% of the donors had a bachelor's degree, and well-educated mothers tend to have better knowledge about and attitude towards milk donation<sup>[21]</sup>. Most of the donors began to donate milk at 1 month postpartum at the earliest, and the number of donors who started to donate decreased rapidly at 3-6 months postpartum. The main reason is probably that most women in China are only given 4–6 months of maternity leave. Once they resume work, their free time and volume of lactation probably decrease dramatically.

Our HMB uses the traditional pasteurization method (62.5°C for 30 min) for sterilization, as a result of which some of the immunological components in donor milk, such as sCD14, may be lost. However, this has little impact on the protein, fat, carbohydrates, some trace elements, and the activity of some enzymes<sup>[22,5]</sup> that are very important and irreplaceable for the development of neonates, especially premature infants. At the initial stage of the establishment of our HMB, donors who passed the pre- and post-pasteurization bacteriological test at the time of the first donation were considered as qualified and were not tested for future donations. However, there is a risk that milk donated by these donors at later time points could be infectious and cause neonatal infection. Therefore, from January 2016, as a result of continuous quality improvements in donor screening, donor milk collection, and donor milk sterilization and storage, DHM donated by qualified donors was first mixed and then pasteurized. In the early stage of quality improvement, each batch of DHM was tested before and after pasteurization every day. The milk extraction process and pasteurization process were considered to be reliable if the batches passed most of the tests, and thereafter, bacteriological testing was conducted every 10 days and batches that failed the pre- and post-pasteurization bacteriological test were excluded.

The DHM in our HMB was only supplied to the neonates in our NICU and was not continued after discharge, and it was provided free of cost. This model is different from that described in previous reports from Thailand and the UK, which provide DHM for non-hospitalized infants<sup>[23-24]</sup>. During the 8-year period, 9,207 newborns received DHM, most of whom were premature infants (80.1%), and the newborns had severe infection, feeding intolerance, and necrotizing enterocolitis. The maximum volume per neonate was 13.7 L, which was used by an extremely premature infant. The duration of use of DHM was mostly less than 15 days, and the average duration was 4.5 days, which is shorter than that previously reported in Scotland<sup>[25]</sup>. This is probably because most mothers have expressed enough breast milk to feed their own babies after a certain time point.

During the COVID-19 pandemic, China implemented strict policies, so we also added COVID-19 nucleic acid testing to the donor screening tests. Visitation was forbidden during newborn hospitalization, and women from other provinces were not admitted to our hospital until recently. From February 4<sup>th</sup> to March 4<sup>th</sup> 2020, breast milk donation and transport to the hospital were not allowed. These policies led to a significant reduction in both the number of donors and volume of DHM. Although this was accompanied by a significant reduction in the number of newborns as well as the demand for DHM, these conditions also led to the depletion of DHM stored at our HMB. Additionally, the breastfeeding rates decreased significantly during this period. However, it is worth noting that there was no case of COVID-19 infection at our hospital during this period.

## Conclusion

The establishment and efficient management of HMBs could support and promote breastfeeding or DHM feeding, and provide better choices and better nutritional treatment options for children who cannot be breastfed by their mothers, critically ill children, or children with certain diseases. Additionally, it is important to raise social awareness about the benefits of breastfeeding or DHM feeding, and actively publicize and provide breastfeeding guidance. Complete, timely, and standard records of data in the HMB database can guarantee its long-term efficiency. It is also necessary to establish a systematic and standardized database at the national level for storing information, analyzing and interpreting various results, supervision and management, and clinical application of research. Over the 8 years of operation of our HMB, through continuous QI, our processes have been gradually finetuned and made efficient, and we will continue to provide DHM to newborns in the future, and provide some recommendations to other HMBs operating in China.

## Declarations

### Authorship confirmation statement

All of the authors contributed to the study and qualify for authorship.

### Acknowledgement

Not applicable.

### Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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## Tables

**Table 1. Costs of HMB Activities Using the Activity-Based Costing Model**

Year	Consumable (RMB)	Testing (RMB)	Labor (RMB)	Equipment (RMB)	Total (RMB)
2013.08-2013.12	25015	38,298	20,000	57,258	140,571
2014	48,138.75	40,670	48,000	-	136,808.75
2015	47,415.25	67,012	48,000	-	162,427.25
2016	125,347.6	53,498	48,000	-	226,845.6
2017	245,467.5	36,285	66,000	-	347,752.5
2018	250,634.3	25,925	84,000	-	360,559.3
2019	178,741.4	44,645	84,000	-	307,386.4
2020	72,108.6	2,495	84,000	-	158,603.6
2021.01-07	48,894.5	1,525	49,000		99,419.5
Total	1,041,762.9	310,353	531,000	57,258	1,940,373.9

HMB: human milk bank;RMB:Renminbi.

**Table 2.Characteristics of Donors.**

		n (%)			n (%)
Reasons for disqualification	Failure to pass the physical examination	168 (67.2)	Number of children	1	1245 (80.1)
	the appearance of donor milk is not well	17 (6.8)		≥2	310 (19.9)
	Failure to pass the pre-pasteurization test	25 (10.0)	Occupation	Company employee	575 (37.0)
	Failure to pass the post-pasteurization test	14 (5.6)		Government employee	197 (12.7)
	Others	26 (10.4)		Self-employed	205 (13.2)
Number of donations	<3	287 (18.5)		Housewife	315 (20.2)
	3–9	549 (35.3)		Others	263 (16.9)
	≥10	719 (46.2)	Age (y)	20–25	126 (8.1)
Preterm/term delivery	Preterm	518 (33.3)		25–30	863 (55.5)
	Term	1037 (66.7)		30–35	426 (27.4)
Time of first donation (postpartum)	<1 wk	153 (9.8)	Education	>35	140 (9.0)
	1 wk to 1 mo	325 (20.9)		Higher than a bachelor's degree	206 (13.2)
	1–3 mo	789 (50.7)		Bachelor's degree	974 (62.6)
	3–6 mo	240 (15.4)		Junior college degree	134 (8.6)
	6–10 mo	48 (3.1)		Lower than a junior college degree	241 (15.5)
Mode of delivery	Vaginal delivery	951 (61.2)			
	Cesarean section	604 (38.8)			

**Table 3.Characteristics of Recipients**

	n (%)			n (%)	
Birth weight (g)	<1000	233 (2.5)	Single/twins/triplet	single	7523 (81.7)
	1000–1500	1398 (15.2)		twins	1664 (18.1)
	1500–2500	5932 (64.4)		≥ triplets	20 (0.2)
	≥2500	1644 (17.9)	Reasons for prescription	preterm	7417 (80.1)
Gestational age (wk)	<28	326 (3.5)		necrotizing enterocolitis	356 (3.9)
	28–31	1179 (12.8)		severe infection or sepsis	718 (7.8)
	31–34	2325 (25.3)		feeding intolerance	516 (5.6)
	34–37	3842 (41.7)	Duration for which DHM was provided	<15 d	8682 (94.3)
≥37	1535 (16.7)	15 d to 1 mo		453 (4.9)	
Time point at which DHM was started (postnatal)	<24 h	4254 (46.2)		>1 mo	72 (0.8)
	24–48 h	3848 (41.8)	longest (d)	67	
	>48 h	1105 (12.0)	average (d)	4.5	

## Figures

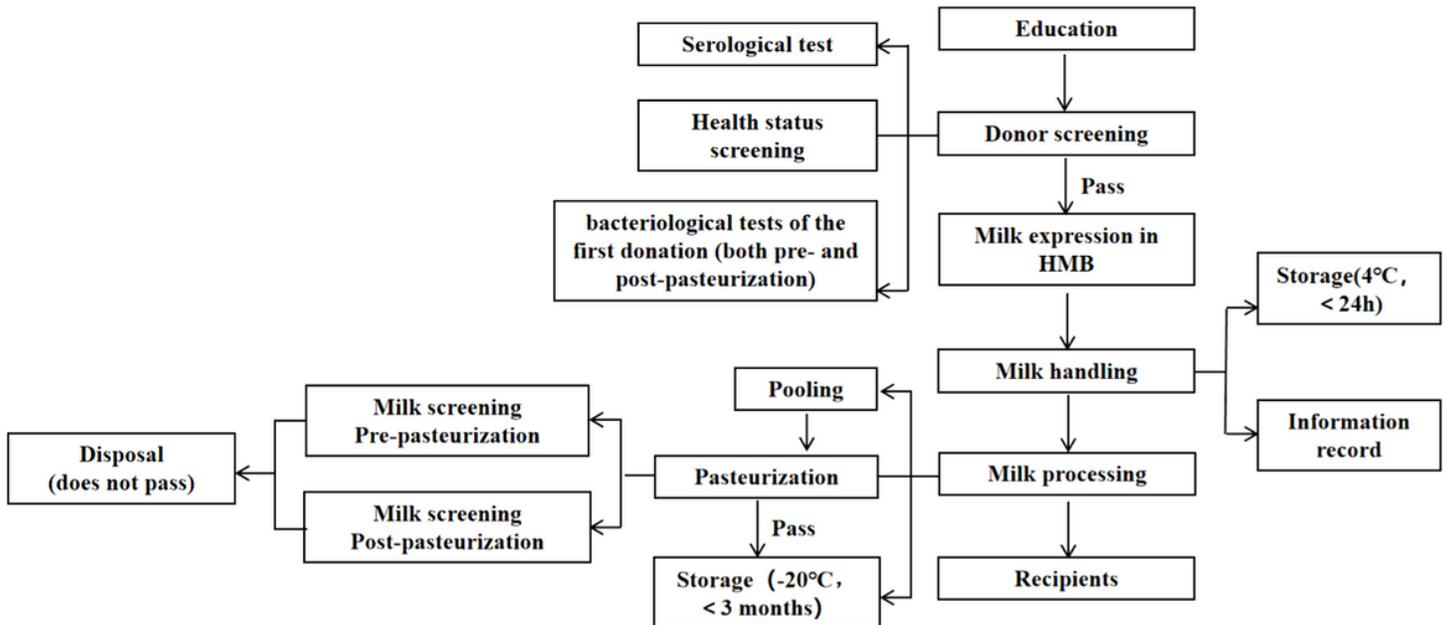
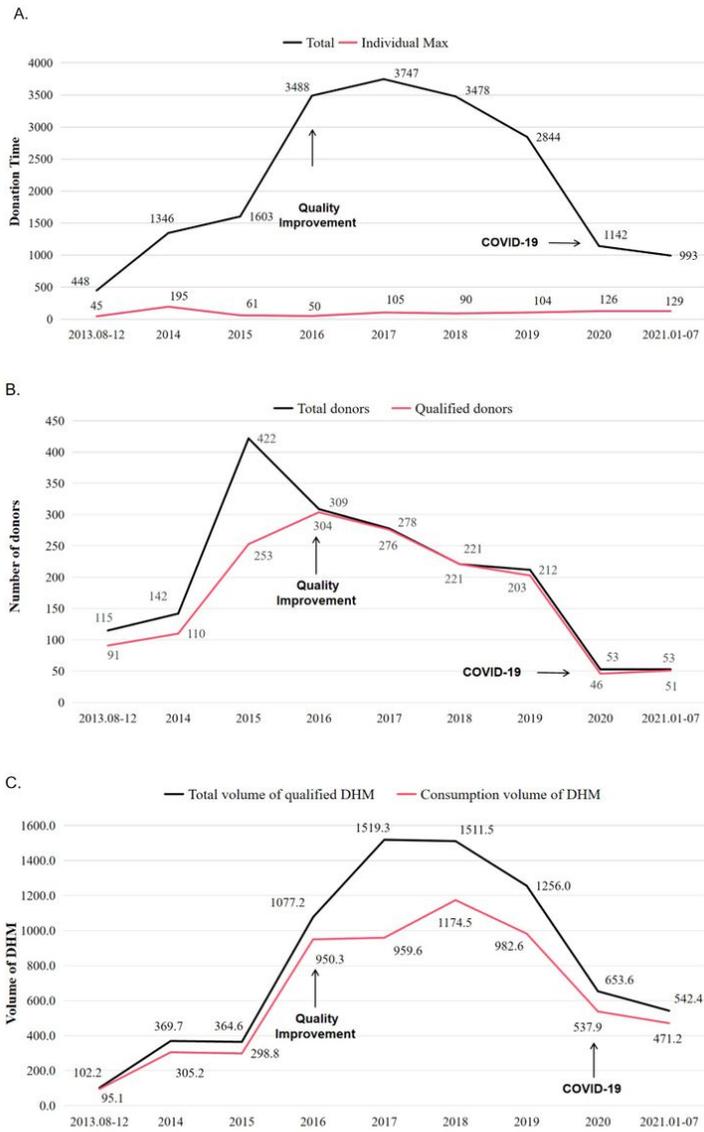


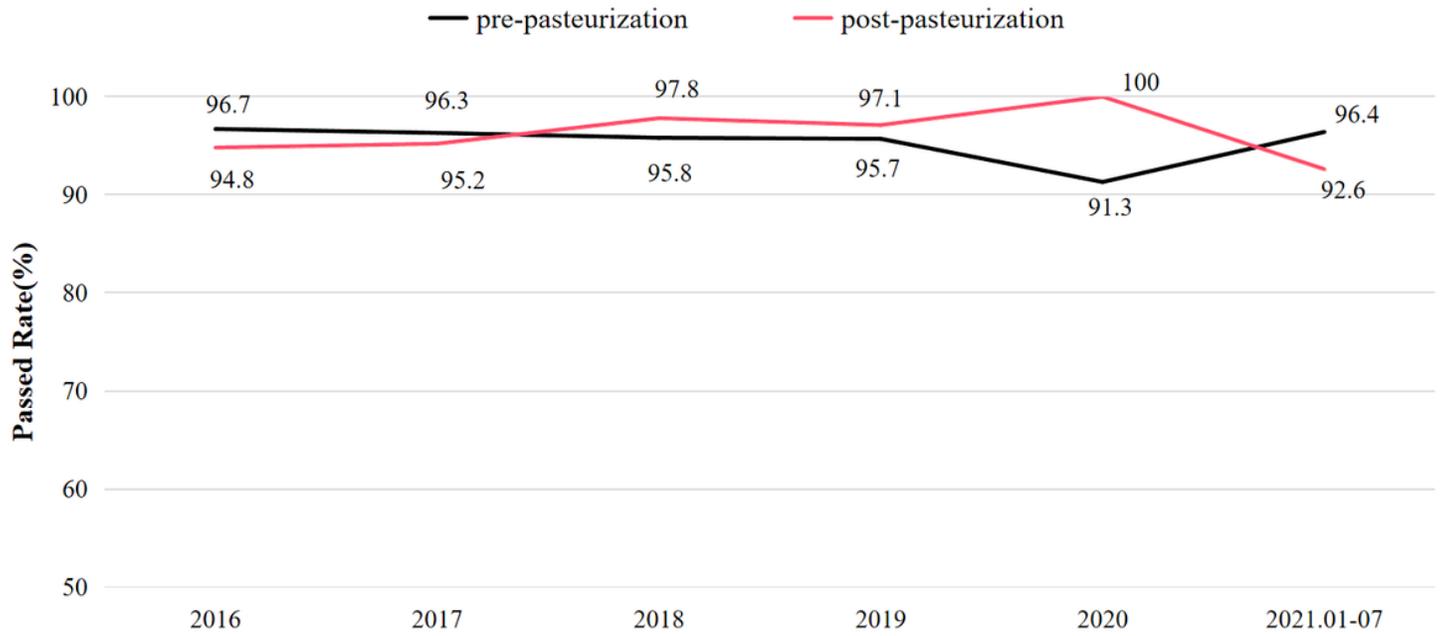
Figure 1

Donation process at our HMB



**Figure 2**

Number of donations (A), number of donors (B), volume of qualified DHM (C) over the 8-year period of operation of our HMB MOM: mother' own milk



**Figure 3**

Proportion (%) of milk that passed the pre- and post-pasteurization bacteriological tests