

## The Third Survey on the Activity of Human Milk Banks in Italy and the Impact of the COVID-19 Pandemic

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### Abstract

**Background:** Growing scientific evidence points to the benefits of human milk for the growth and development of a newborn. Compelling evidence has confirmed the benefits not only for full-term babies but also for preterm infants.

**Objective:** This survey was planned by the Italian Ministry of Health together with the Italian Association of Donor Human Milk Banks (AIBLUD) and aimed to evaluate the activity of human milk banks (HMBs) in Italy in the period 2018-2020, analyzing several items and the impact of the COVID-19 pandemic.

**Methods:** Following the two surveys performed in 2012 and 2016, a third survey was planned in the year

2021 to evaluate possible changes in the activity of the Human Milk Banks (HMBs) operating in Italy. A questionnaire was sent to all the 41 HMBs officially operating in Italy in the year 2021 with the purpose to obtain national data concerning milk banks activity, number of donors, volume of human milk collected, and other information related to the years 2018, 2019 and 2020. Additional questions related to the impact of the COVID-19 on the activity of HMBs in the year 2020 were included.

Therefore the questionnaire proposed in this third survey collected fundamental data on the donation of human milk with the implications related to the COVID-19 pandemic.

**Results:** 90% of the banks (37/41) responded to this survey. The collected data confirm the results of the second survey (2016), with a high level of adherence to the Ministerial Guidelines and the AIBLUD recommendations. The application of the principles of the HACCP system continues to improve (89%), while in the last three years there has been a sharp decline in the home collection service for donor human milk (68%). This decline is mainly linked to the interruption of this service due to the limitations imposed by the pandemic. In 2020 (the year of the COVID-19 pandemic) there was a clear reduction in the number of donors with a return to the values of 2016. The volumes of milk collected, and the average duration of donation, however, remained high. The reasons linked to the reduction in the number of donors are described.

**Conclusion:** This survey underlines the high quality standard of Italian HMBs and the usefulness of this service for the national health policy. Despite the difficulties due to the COVID-19 pandemic, the Italian HMBs have maintained an efficient and safe service and have guaranteed the collection of satisfactory volumes of donor milk. Lack of information represents the most important barrier to the donation of human milk.

## Background

The particular nutrient composition, hormonal and enzymatic components, anti-infective and growth factors of human milk make it a unique and inimitable nutrient<sup>1</sup>. There are no doubts that human milk is the best nutrient for term infants. Compelling evidence confirmed the substantial benefits not only for term, but also for preterm infants<sup>1-6</sup>.

The mother's own milk is the first choice for all neonates including preterm infants: when it is not available or not sufficient, donor human milk is a valid alternative. The first investigation conducted in Italy in the year 2000<sup>7</sup> was mainly useful to point out the number of active Italian HMBs and to reveal high variability in the operating procedures.

As a consequence of that survey, a task-force of the Italian Society of Neonatology wrote and published the first Italian Guidelines for the Establishment and Operation of a Donor Human Milk Bank (2002)<sup>8</sup>, followed by updated editions in the years 2007<sup>9</sup>, 2010<sup>10</sup>, 2012<sup>11</sup> and by specific recommendations in 2021<sup>12</sup>. In the meantime, as a possible consequence of the increased interest to human milk donation due to these updated publications, the number of HMBs in Italy increased considerably, their organization improved, and so did their standard procedures.

The Italian Association of Donor Human Milk Banks (Associazione Italiana Banche del Latte Umano Donato, AIBLUD) was founded in 2005. It currently consists of 41 HMBs (Figure 1), whose management should follow the Italian Guidelines. Among the goals of the association, technical update and scientific activity play a major role.

After publication of the Italian Guidelines<sup>8-11</sup>, the 2012<sup>13</sup> and 2016<sup>14</sup> surveys on Italian HMBs led to a nation-wide improvement: new banks were established and others considered not very efficient were shut down. In 2013 the Italian Ministry of Health published National Recommendations on HMBs, based on the Italian



Figure 1. The 41 Human Milk Banks in Italy (2022)

Table 1. The Questionnaire sent in the year 2021 to the 41 human milk banks operating in Italy

<p><b>NAME OF PERSON COMPLETING THIS QUESTIONNAIRE</b></p> <p><b>MILK BANK NAME and ADDRESS</b></p> <p><b>NAME OF PERSONS RESPONSIBLE</b> (manager and clinical)</p>
<p><b>STATISTICS</b></p> <p>Number of donors of donor human milk in years 2018, 2019 and 2020</p> <p>Volume of donor milk collected in years 2018, 2019 and 2020</p> <p>Average length of donation in years 2018, 2019 and 2020</p> <p>Number of infants fed with donor milk in years 2018, 2019 and 2020</p>
<p><b>HOME COLLECTION SERVICE</b></p> <p>Did you have a transport service for home collection of donor milk in years 2018, 2019 and 2020?</p>
<p><b>HACCP (HAZARD ANALYSIS AND CRITICAL CONTROL POINT)</b></p> <p>Did you apply the principles of the HACCP system in years 2018, 2019 and 2020?</p>
<p><b>IMPACT OF COVID-19</b></p> <p>What were the effects of the COVID-19 pandemic on the bank's activity?</p> <p>In case of decreased number of donors and/or reduced volume of milk collected, which were the main reasons?</p>

Guidelines<sup>15</sup>.

## Methods

In the year 2021, a reduced questionnaire compared to those of the previous surveys (Table 1) was used to obtain national data concerning milk banks activities, the number of donors, the volume of human milk collected, and other information related to years 2018, 2019 and 2020. Additional questions related to the impact of COVID-19 on the activity of HMBs in our country were included. In 2012, 28 HMBs were involved<sup>13</sup>, 35 banks in the year 2016<sup>14</sup> and 41 banks in the 2021 survey (three-year period 2018-2020). All the items were collected in a spreadsheet that AIBLUD sent via e-mail to the banks.

The main questions were related to the number of donors and to the amount of donor milk collected in the three-year period 2018-2020. Other questions focused on the use of the HACCP<sup>16</sup> system and on transport service of milk collection at home. The questions regarding COVID-19 were related to the effects of pandemic on the number of donors and volumes of donor milk collected with investigation of the causes of the reduction, when present.

## Results

The data of this third survey refer to 37 banks out of 41 (90% of the banks involved), a figure comparable to that for 2012<sup>13</sup> and 2016<sup>14</sup>, where data were collected from 28 out of 32 banks (2012) and 32 out of 35 (2016).

Table 2 shows the two fundamental questions that had highlighted poor results in the previous surveys: the application of the principles of the HACCP system, and the home delivery service. In fact, as regards the other data concerning the management of the bank (staff, equipment, infectious disease tests, etc.), the optimal adherence to the Ministerial Guidelines and the AIBLUD Recommendations was already confirmed. The percentage of responses of the present survey is comparable with those of 2012 and 2016 surveys.

It can be noted that the application of the principles of the HACCP system continues to improve,

while in the last three years there has been a sharp decline in the home milk collection service. This is due, in several cases, to the suspension of this service by some HMBs due to limitations imposed by the COVID-19 pandemic.

Tables 3 and 4 show the detailed data related to the individual years, again compared with the two previous surveys (years 2012 and 2016). It is clear that in the period preceding the COVID-19 pandemic (2018 and 2019) there was a high increase in the donation of milk; in 2020, on the other hand, there was a clear reduction in the number of donors with a return to the values of 2016. The volume of milk collected and the average duration of the donation, however, remained high.

Finally, in this survey (Table 4) we have taken into consideration the number of infants fed with donor milk. The data show a use of donor milk especially in feeding very low birth weight (VLBW) infants and pathological newborns over 2499 g. In recent years, in Italy there has been a marked decline in the number of live births (Table 5) with a simultaneous drop in the total number of infants fed bank milk; the incidence of these newborns on the total number of live births is similar. However, if we evaluate the VLBW infants, the incidence of those fed with bank milk is slightly reduced from 2016 (27.3%) to 2020 (26.0%).

### *Impact of COVID-19*

HMBs' activities have been affected by the COVID-19 pandemic, caused by the new coronavirus called SARS-CoV-2. In December 2019, when it appeared in China<sup>17</sup>, the severity of the disease and its possible impacts on global health were not known.

On 11 March 2020 the World Health Organization (WHO)<sup>18</sup> declared the SARS-CoV-2 pandemic, with virus transmission occurring by air.

Therefore the adoption of hygiene and behavioral measures was recommended, but such measures had also to take into account the social aspects and beliefs of the population<sup>19</sup>. The year 2020 presented the most critical issues at a health and social level.

The spread of the infection in Italy was

Table 2. Comparison of data with previous surveys

Years	2012	2016	2018-2020
Number of Banks answering the questionnaire	25 out of 28	32 out of 35	37 out of 41
Application of the principles of the HACCP* system	72%	84%	89%
Milk collection service at home by the bank	64%	75%	68%

\*HACCP = Hazard Analysis and Critical Control Points

Table 3. Comparison of data with previous surveys

Years	First Survey	Second Survey	Third Survey		
	2012	2016	2018	2019	2020
Number of donors	975	1336	1606	1621	1331
Volume of donor milk collected (liters)	9448	9181	12373	14051	12461
Average volume of milk collected per donor (liters)	9.7	6.9	7.7	8.7	9.4
Average length of donation (days)	*	142	99	100	90

\* Not requested

Table 4. Number of infants fed with donor milk in 2016-2020

Birth weight	2016 (n.)	2018 (n.)	2019 (n.)	2020 (n.)
< 1500 g	1299	1014	993	946
1500-2499 g	1447	1611	1613	1379
> 2499g (in NICU*)	1049	806	889	1024
Healthy term infants**	1192	553	685	587
Total	4987	3984	4180	3936

\* NICU = Neonatal Intensive Care Unit

\*\* Healthy term infants: term infants needing an increased intake of liquids in the first 48-72 hours of life due to hyperbilirubinemia, hypoglycemia or excessive weight loss

Table 5. Number of live births and VLBW infants fed with donor human milk in Italy

Years	Total number of live births*	N. of infants fed with donor milk	Total number of VLBW infants born in Italy	N. of VLBW infants fed with donor milk
2016	474,925	4987 (1.05 %)	4749	1299 (27.3 %)
2018	442,676	3984 (0.90 %)	4427	1014 (22.9 %)
2019	421,913	4180 (0.99 %)	3797	993 (26.1 %)
2020	404,260	3936 (0.97 %)	3638	946 (26.0 %)

\*Source: Italian Ministry of Health (<https://www.salute.gov.it>)

Table 6. Effects of the COVID-19 pandemic on the activity of Italian Human Milk Banks, and main causes

Effects	N. banks
Reduction in the number of donors and reduction in the volume of donor milk	20 (54%)
Increase in the number of donors	5 (14%)
Increase in the volume of donor milk	7 (19%)
Unchanged volume of donor milk	7 (19%)
Causes	
Inability to exit for lockdown	14 (38%)
Inability to access the bank	12 (32%)
Operational complications at the bank (tests, mask, etc.)	8 (22%)
Suspension of the home collection service	11 (30%)
Fears of donors to go to the hospital to donate milk	17 (46%)

particularly extensive (Agenas<sup>20</sup>): 2,000-3,000 per 100,000 inhabitants in the south up to 4,000-5,000 per 100,000 inhabitants in northern Italy.

WHO<sup>21</sup> issued indications for HMBs, followed by recommendations from the European Milk Bank Association (EMBA) and AIBLUD<sup>22</sup>. The SARS-CoV-2 virus, like other coronaviruses, is inactivated by Holder pasteurization<sup>23-25</sup>. However, the COVID-19 pandemic caused difficulties on the activity of the majority of HMBs in Italy: 20 banks out of 37 (54%) saw a reduction in the number of donors and in the volume of donor milk collected, while 5 banks (14%) reported an increase in the number of donors (Table 6).

The reasons linked to the reduction in the number of donors are interesting: in particular, the suspension of the home collection service by 11 banks had a severe negative impact on the activity of the banks, as explained by the operators. The main reasons for the negative effects were limitations on access to the bank and suspension of the home collection service.

## Discussion

Many countries felt the need to standardize HMBs activity through specific guidelines, but surveys confirming the compliance with the guidelines are not easy to find. A web-based questionnaire was developed by the European Milk Bank Association (EMBA) Survey Group<sup>26</sup>, for distribution to the European HMBs. A total of 123 replies (response rate = 57%) from 22 out of the 26 European countries (85%) were received.

An example of a national continuous control system is the Instituto Fernandes Figueira-Fundação Oswaldo Cruz (FIOCRUZ), the Brazilian human milk net<sup>27</sup>. The data collected from Brazilian banks are very useful for the net and for the government. A study performed in the US shows the lack of standardization in common practices among the HMBs belonging to the Human Milk Banking Association of North America (HMBANA)<sup>28</sup>. There is a need for a centralized donor human milk data repository in order to produce useful generalizable information, to promote new researches and to improve the quality of donor human milk.

In Italy, the Italian Association of Donor Human Milk Banks (AIBLUD) managed in 2012 to get all the active banks of our country involved in the national project and to also monitor their activities<sup>13,14</sup>. In 2013, the cooperation between AIBLUD and the Italian Ministry of Health led to the publication in the Official Gazette of the Italian Republic of the "Italian National Recommendations for the Organization and Management of HMBs as a Tool for the Protection, Promotion, and Support of Breastfeeding"<sup>15</sup>. The purpose of these recommendations was to share specific rules and to define specific controls for the activities of HMBs in Italy.

This cooperation also allowed the collection of data of the bank's activities in Italy in the year 2012<sup>13</sup>. A further combined survey (AIBLUD and Italian Ministry of Health) was realized in the year 2016<sup>14</sup>. The results of this third survey refer to the three-year period 2018-2020, taking also into consideration the effects of the COVID-19 pandemic on the activity of the banks in the year 2020.

Since 2018, AIBLUD is organizing regular training courses for the management of HMBs (2-3 local courses per year in different regions). These courses confirm that the activity of Italian human milk banks is consistent with the indications of the specific Italian guidelines.

The main recurring problems are linked to the application of the principles of the HACCP system and to the home collection service of donor milk.

Therefore, this survey evaluates these two critical points together with the variable data of the banks' activity (number of donors, volumes of donor milk, number and type of infants fed with donor milk).

The number of Italian HMBs has increased compared to 2016 (5 new banks), in particular in northern Italy (Lombardy and Veneto regions have the highest number of banks). Southern Italy remains lacking in this service, with a limited number of HMBs operating in the territory.

One of the most important tasks for a human milk bank is the service for collecting and transporting human milk from donors' home to the bank. In the three-year period 2018-2020, in Italy nearly one third of the banks

(32%) did not provide this service, a value even worse than that obtained in 2016 (25%), mainly attributable to the difficulties related to the COVID-19 pandemic.

The Italian guidelines strongly suggest the application of the principles of the HACCP system<sup>16</sup>.

Following these recommendations, 33 out of 37 of our banks (89%) use this system for safety and quality control; this figure is better than that recorded in 2012 and 2016, but we still believe it should be 100%.

Compared to the years 2012 and 2016, in the years 2018 e 2019 HMBs collected an increased volume of milk (35-53%), with a higher number of donors (Table 3). In 2020, the year of the COVID-19 pandemic, these values decreased.

The strong commitment of the bank staff is confirmed by the number of infants fed with donor milk. In the three-year period 2018-2020 there was a decline of infants receiving donor human milk, which is attributable to the decline in births. The percentage of infants fed with donor human milk remains around 1% of live births. This figure shows that we are still a long way from the extensive use of donor milk in VLBW infants and in sick infants (Table 4 and 5). Many scientific evidences confirm the benefits of the use of human milk for VLBW infants<sup>1-6</sup>.

Regarding the impact of COVID-19, 2020 data show the difficulties of milk banks: fewer donors and lower volumes of donor milk (Table 6).

Despite the pandemic, some banks had more donors and larger volumes of donor milk than in previous years. This depends on the context and the accessibility to health services. In fact, a virtual collaborative network<sup>29</sup> with more than 80 donor HMB leaders from 36 countries identified seven pandemic-specific and highly context-dependent vulnerabilities: the provision of services, the interruption of the pre-screening, the availability of the donor human milk, logistics, the communication, safe management, and emergency planning.

Also a survey of donor HMBs in North America<sup>30</sup> studied the impact of the COVID-19 pandemic on 30 human milk bank services: most banks (65%) reported an

increase in their numbers of donors and in the volume of milk collected. These findings show that the pandemic had no negative impact in many North America milk banks.

The implementation of the Italian guidelines and the continuous cultural stimulus with training courses by AIBLUD are probably among the leading causes of the opening of new banks in our country. From 2012 to 2021, nine more HMBs started their activity in Italy. The widespread application of the Italian guidelines is relevant and reassuring. Italian banks are always attentive to traceability, control of donors, bacteriological checks, pasteurization method, storage, thawing, type of containers, and application of the HACCP system. The results of this survey show that it is mandatory to monitor regularly the activity of the banks, and AIBLUD is particularly involved in this surveillance.

In spite of the 41 HMBs operating in our country (Italy has the highest number of HMBs in Europe), the volume of donated human milk is still not enough to cover the needs of all the VLBW infants born in Italy. In 2019, 3290 women completed a web-based survey aimed to explore Italian women knowledge and attitude towards human milk donation<sup>31</sup>. Altruism and having an abundant milk supply were found to be the most important facilitators for women to donate their milk. Social classes and economic conditions did not have any influence on the answer of the interviewee women. The most important barrier to donation was the lack of information on donation and HMBs activity and organization. This problem could be solved planning education actions, not only during pregnancy, but especially within the communities and the school programs. People should be educated about the “art of donation” from a very young age, starting in primary school and continuing in secondary school, including University campaigns in order to create a deep awareness. The same policy can be used to solve the problems of human milk donation when ethical and religious issues are involved, like among Muslim women.

## Conclusions

This survey underlined the capacity of the Italian

HMBs to overcome the difficulties linked to the COVID-19 pandemic and confirmed some critical aspects, such as the use of the HACCP system and the home-donor milk collection service. This survey confirmed the quality of the service and its usefulness for Italian health policy; it also highlighted that the act of donation is part of the life of a community and must therefore face all social, economic, and health difficulties.

However, in Italy, infants fed with donor milk are still too few: only 1% of live births. It is one of the reasons why our association, AIBLUD, keeps spreading the culture of donation and training courses for bank operators. It would be interesting to compare our results with the experiences of other countries in order to improve the management and the activity of the HMBs.

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The authors declare that no conflict of interest exists.

This review represents the overall activity of the participating centers and ensures their privacy.

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