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## Research Article

## The second Italian human milk banks survey

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## ABSTRACT

**Background:** In the latest decades some compelling evidence confirmed the substantial benefits of using human milk, especially for preterm infants [1-5]. Donor human milk is a valid alternative.

**Objective:** This survey aimed to evaluate the activity of the human milk banks in Italy, analysing several items.

**Methods:** The Italian Association of Donor Human Milk Banks (Associazione Italiana Banche del Latte Umano Donato, AIBLUD) was founded in 2005. It currently consists of 35 human milk banks (Figure 1), whose management should follow the Italian Guidelines. Among the goals of the association, scientific work plays a major role.

After publication of the Italian Guidelines, the 2012 survey on Italian human milk banks also led to a nationwide improvement: some banks were established, others that were considered inactive were shut down [11]. In 2013 the Italian Ministry of Health published the national recommendations, based on the Italian Guidelines [12].

**Results:** 91% of the banks (32/35) responded to this second survey. Table 2 shows the average number of hours per week dedicated to the milk bank activity. This data varies greatly among the banks, as it did in 2012. The majority of the banks keeps having approximately 6 hours a day of work

**Conclusion:** This second survey gave AIBLUD and the Italian Ministry of Health important information on the Italian human milk banks, overcoming their difficulties and correcting some negative aspects.

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## Background

Growing scientific evidence indicates the benefits of human milk for appropriate growth and development of a newborn infant. The particular nutrient composition, hormonal and enzymatic components, anti-infective and growth factors of human milk make it a unique and inimitable nutrient [1]. There are no doubts that human milk is the best nutrient for term infants. In the latest decades some compelling evidence

confirmed the substantial benefits of the use of human milk also for preterm infants [1-5]. 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. An investigation conducted back in 2000 was mainly useful to point out the number of active Italian human milk banks and to reveal high variability in the operating procedures [6].

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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), followed by updated editions in the years 2007, 2010 and 2012 [7-10]. In the meantime, as a possible consequence of the increased interest to the problem due to these updated publications, the number of human milk banks in Italy increased, their organization improved and so did their procedure standards.

The Italian Association of Donor Human Milk Banks (Associazione Italiana Banche del Latte Umano Donato, AIBLUD) was founded in 2005. It currently consists of 35 human milk banks (Figure 1), whose management should follow the Italian Guidelines. Among the goals of the association, scientific work plays a major role.

1. After publication of the Italian Guidelines, the 2012 survey on Italian human milk banks also led to a nation-wide improvement: some banks were established, others that were considered inactive were shut down [11]. In 2013 the Italian Ministry of Health published the national recommendations, based on the Italian Guidelines [12].



**Figure 1:** Human Milk Banks in Italy (2018)

## Methods

A similar questionnaire to the previous one of 2012 (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 2016. The main questions were the same as those of 2012; moreover, we requested the number of children fed with donor milk and the average length of donation. There were involved 28 banks in 2012 and 35 banks in the year 2016. All the items were either collected in a database of the Italian Ministry of Health website, or in a spreadsheet that AIBLUD sent via e-mail to the banks.

We asked the number of working hours per week, the number of rooms dedicated to bank management (location for machines and for collection and storage of donor milk), the number of pasteurizers, the number of donors, and the amount of donor milk collected in 2016. Additional

questions concerned the supply of human milk to other hospitals, the availability of a database and milk traceability from donor to recipient. We also investigated the general processing, the screening of donors for hepatitis B, hepatitis C, HIV and the bacteriological tests on donor milk. Other questions focused, for example, on the pasteurization method, storage, type of containers, use of the HACCP system and transport service of milk collection at home [13]. The differences between the two surveys were calculated with the  $\chi^2$  test using Epi Info 7.2 software [14].

## Results

91% of the banks (32/35) responded to this second survey. Table 2 shows the average number of hours per week dedicated to the milk bank activity. This data varies greatly among the banks, as it did in 2012. The majority of the banks keeps having approximately 6 hours a day of work dedicated to the activity, a number associable to the reduced staff of the centres. In 2016, 28 out of 32 milk banks (19/25 in 2012) had at least one room available for their activity. The Italian guidelines recommend a standard suitable for the bank's activity: six hours and one room dedicated are really few. Concerning the number of pasteurizers (Table 2), the majority of the Italian banks (80%) has only one pasteurizer; the data of 2012 is similar in 2016. This is still a limiting factor, because in case of damage of the machinery, the main activity of the bank stops. All the banks use Holder pasteurization method for heat treatment of human milk (62,5°C for 30 minutes). The number of available breast pumps largely varied (range 2-28), as did the number and the type of freezers. However, the 2016 data show an enrichment of the equipment availability: 62% (44% in 2012) have more than 5 breast pumps, 72% (32% in 2012) have more than 2 freezers. The storage temperature is still -20°C. The system data collection has improved, and the use of disposable bottles has increased (p-value < 0,05 for both). The two surveys confirm the focus on supply of donor milk to other hospitals and on the traceability from donor to recipient. In 2016, 16% of the banks still had not applied the Hazard Analysis and Critical Control Points (HACCP) system. Moreover, 25% of the banks did not guarantee the collection service of donor milk at home.

Table 3 shows the number of donors, volume of milk collected (in liters), and average volume of milk collected per donor (in liters). Compared to 2012, in 2016 human milk banks collected a lower volume of milk, but with a higher number of donors. The table also shows the volume of discarded donor milk, the volume of donor milk surplus unused and the average length of the donation (in days) in 2016. In regard to the donors' screening and testing, and the microbiological checks on donor milk, all the human milk banks (100%) check donors for smoking, alcohol, drugs, medicines and for viruses of hepatitis and HIV (Table 4). Little attention is paid to other infections. Also, donor milk microbiological checks reach 100% both on the first donation and on occasional ones, with high statistical significance.

Finally, in this survey (Table 5) is taken into consideration the number of infants fed with donor milk in 2016. 28 centres treated in total 1299 VLBW (very low birth weight, under 1500 g) infants and 1447 infants of birth weight 1500-2499 g. Food management with donor milk is also for infants over 2499 g (22 centres with a total of 1049 infants) and also for healthy term babies (10 centres with a total of 1192 infants)

**Table 1:** The Questionnaire sent to the 35 human milk banks operating in Italy for the year 2016

<b>NAME OF PERSON COMPLETING THIS QUESTIONNAIRE</b>
<b>MILK BANK NAME and ADDRESS</b>
<b>NAME OF PERSONS RESPONSIBLE</b> (manager and clinical)
<b>IS THE MILK BANK LINKED TO A HOSPITAL?</b>
<b>STAFF</b> Staff working in the milk bank and hours dedicated to the milk bank
<b>EQUIPMENT</b> Rooms (n.); pasteurization machines (n.); breast pumps (n.); freezers (n.)
<b>STATISTICS</b> Does the milk bank keep statistics? Number of donors of donor breast milk in 2016 Volume of donor milk collected in 2016 Volume of donor milk discarded in 2016 Volume of donor milk surplus unused in 2016 Average length of donation in 2016 Number of infants fed with donor milk in 2016 Do you supply donor milk to other hospitals? (if yes, how many hospitals?) Do you keep a data base of donors? Can donor milk be tracked from donor to recipient?
<b>CHECKS ON DONORS</b> Are donors screened for smoking, alcohol, drugs, medicines, HIV risk? Are donors tested for hepatitis B, hepatitis C, HIV?
<b>CHECKS ON DONOR MILK</b> Is all milk tested bacteriologically before pasteurization? If no, is milk tested on first donation or every donation or occasionally?
<b>METHOD OF PASTEURIZATION</b> HOLDER (62.5°C for 30 minutes): Yes/No
<b>METHOD OF STORAGE</b> Is milk frozen after pasteurization at -20°C?
<b>TYPE OF CONTAINER</b> Do you use disposable bottles?
<b>HOME COLLECTION SERVICE</b> Do you have transport service for home collection of donor milk?
<b>HACCP (HAZARD ANALYSIS AND CRITICAL CONTROL POINT)</b> Do you use HACCP? Do you have a handbook for HACCP?

**Table 2:** General management of Italian Human Milk Banks

<b>General management</b>	<b>2012</b>	<b>2016</b>	<b><math>\chi^2</math> test</b>
<b>N. Banks</b>	<b>25</b>	<b>32</b>	
Staff dedicated: working hours per week (average)	42	44	n.s
Rooms (minimum one)	76%	88%	n.s
Pasteurization machines n. > 1	20%	19%	n.s
Holder method's use	100%	100%	n.s
Breast pumps n. > 5	44%	62%	n.s
Freezers n. > 2	32%	72%	p < 0,05
Temperature of storage - 20 °C	100%	100%	n.s
System data collection	84%	100%	p < 0,05
Use of disposable bottles	78%	100%	p < 0,05
Supplied to other hospitals	56%	47%	n.s
Tracking from donor to recipient	88%	94%	n.s
Home collection service	64%	75%	n.s
Use of HACCP* system	72%	84%	n.s

\*HACCP = Hazard Analysis and Critical Control Points

**Table 3:** Shows the number of donors, volume of milk collected (in liters), and average volume of milk collected per donor (in liters). Compared to 2012, in 2016 human milk banks collected a lower volume

	2012	2016
<b>N. Banks</b>	<b>25</b>	<b>32</b>
Donor number	975	1336
Volume of donor milk collected (liters)	9448	9181
Average volume of milk collected per donor (liters)	9.7	6.9
Volume of donor milk discarded (liters)	**	465
Volume of donor milk surplus unused (liters)	**	153
Average length of donation (days, range)	**	142 (38-952)

\*\* Not Required

**Table 4:** Donor's screening and testing with microbiological checks on donor milk

	2012	2016	$\chi^2$ test
Donors screened for smoking, alcohol, drugs, medicines, HIV risks	96%	100%	n.s
Donors tested for Hepatitis B and C, HIV	96%	100%	n.s
Microbiological checks on donor milk on first donation	68%	100%	p < 0,05
Microbiological checks on donor milk occasionally	28%	100%	p < 0,05

**Table 5:** Number of infants fed with donor milk in 2016

Birth weight	Centers (n.)	N. Infants (average, range)
<1500 g	28	1299 (46, range 13-100)
1500 – 2499 g	28	1447 (52, range 5-211)
>2499 g	22	1049 (48, range 4-53)
Healthy term	10	1192 (119, range 44-82)

## Discussion

Many countries felt the need to standardize human milk banks activity through specific guidelines, but surveys confirming the compliance with the guidelines are not easy to find. In Europe, despite the presence of an important association of banks (EMBA), it has not yet been possible to monitor their activity [15]. In Japan, for example, the need to monitor the activity of Japanese banks with a questionnaire was reported [16].

An example of a national control system is the Instituto Fernandes Figueira-Fundação Oswaldo Cruz (FIOCRUZ), the Brazilian human milk net [17]. The data collected from Brazilian banks are very useful for them and for the government. A study performed in the US shows the lack of standardization in common practices among the human milk banks belonging to the Human Milk Banking Association of North America (HMBANA) [18]. There is a need of 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 project and to also monitor their activities [19]. In 2013, the cooperation between AIBLUD and the Italian Ministry of Health led to the creation of the "Italian National Recommendations for the Organization and Management of Human Milk Banks as a Tool for the Protection, Promotion, and Support of Breastfeeding" published in the Official Gazette of the Italian Republic [7]. Its purpose was to share specific rules and to define specific controls for the activities of human milk banks in Italy.

This cooperation also allowed the collection of data of the bank's activities: it is thus possible to obtain data for 2016. The results of this survey show that the number of Italian human milk banks increased compared to 2012 (7 new banks), but on average the banks are still understaffed and have a limited number of pasteurizers. The number of breast pumps and freezers has increased if compared to 2012, although this is relevant only for the freezers: 72% vs 32% have more than 2 freezers. It is interesting to note that about half of the banks (47%) supply donor milk to other hospitals, which only cover transport costs. The traceability of the final product is very important in human milk banks activity, and 94% of the banks takes this aspect into careful consideration. Fresh mother's own milk, when administered within 24 h of collection, does not require routine culturing or heat treatment. Instead, donor human milk needs to be microbiologically checked and should undergo heat treatment. The Italian Guidelines suggest testing regularly the pasteurized milk at first donation, and for later donations, only when the donor does not seem to guarantee the appropriate hygienic conditions. In all other cases, testing should be periodical and random. In 2016 all the banks followed these recommendations. In some regions there are examples of regional network: Toscana (6 banks), Trentino-Alto Adige (Trento supplies donor milk to Bolzano) and Emilia-Romagna (Cesena supplies donor milk to Rimini) were already working in 2012; in 2016 similar collaborations were reported in regions such as Piemonte, Valle d'Aosta and Lombardia. These models are not yet present in southern Italy, where there are few banks, reflecting the Italian socio-economic differences. One of the most important tasks for a human milk bank is the service for collecting and transporting milk from home. In 2016 in Italy 25% of the banks still did not provide this service. The Italian guidelines strongly suggest the use of the HACCP system

[13]. Following these recommendations, 27 out of 32 of our banks (84%) use this system for safety and quality control; this data is better than in 2012, but we believe that it should be 100%.

Compared to the year 2012, in 2016 human milk banks collected a lower volume of milk, with non-significant differences, but with a higher number of donor (37% more). It is interesting to see the average length of donation: 142 days in 2016. The progressive increase of the number of donors without an increase of donor milk can be attributed to the bank staff involving an increasing number of donors, action apparently not followed by a high production of human milk.

The strong commitment of the bank staff is confirmed by the number of infants fed with donor milk in year 2016 (Table 5): food management with donor milk is also for infants over 2499 g (22 centers with a total of 1049 infants) and for healthy term babies as well (10 centers with a total of 1192 infants). Many scientific evidences confirm the benefits of the use of human milk for VLBW infants [1-5]. The mother's own milk is the first choice for these neonates; when it is not available or not sufficient, donor human milk is a valid alternative.

The implementation of the Italian guidelines and the continuous cultural stimulus from AIBLUD are probably among the leading causes of the opening of new banks in our country: in fact, from 2012 to 2017 seven more human milk banks started their activity in Italy. The widespread application of the Italian guidelines is relevant and reassuring. Italian banks are always attentive to traceability, controls 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 the activities of the banks, and AIBLUD is particularly involved in this surveillance.

## Conclusion

This survey confirmed the willingness of Italian human milk banks to overcome their difficulties (especially due to the reduced staff) and to improve some difficult aspects, such as the use of HACCP system and the collection service of donor milk at home. However, in Italy, VLBW infants fed with donated milk are still too few: in 2016 they were 1299 out of about 4500 (only 29%). 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 human milk banks.

## Authors' Note

The Italian Association of Donor Human Milk Banks (Associazione Italiana delle Banche del Latte Umano Donato, AIBLUD) consisted of the following members: Daniela Rossini, Ancona; Letizia Magi, Arezzo; Marzia Tarantino, Bari; Luigi Tommaso Corvaglia, Bologna; Elisabetta Fabian, Camposampiero; Antonella Buda, Cesena; Mariangela Conte, Chieti; Federica Ruffolo, Cosenza; Fina Belli, Firenze; Mariarosaria Matera, Grosseto; Alessandra Manfredi, Lido di Camaiore; Raffaele Domenici, Lucca; Pasqua Maria Piemontese, Milano Mangiagalli; Orlando Cipolla, Milano M. Melloni; Flippo Porcelli, Milano San Giuseppe; Paolo Torelli, Modena; Chiara Giovannozzi, Moncalieri; Gennaro Salvia, Napoli; Iwona Kazmierska, Palermo; Stefania Troiani,

Perugia; Julia Bomben, Pordenone; Giancarlo Gargano, Reggio Emilia; Daniela Marino, Roma; Pasqua Anna Quitadamo, S. Giovanni Rotondo; Olinda Gasparre, Siena; Elisabetta Punziano, Torino; Mariangela Zancanella, Trento; Marika Buffo, Treviso; Viviana Gregorutti, Udine; Elena Uga, Vercelli; Silvana Lauriola, Verona; Barbara Gasparin, Vicenza.

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