



EDITORIAL

## Risks associated with the uncontrolled use of donated breast milk<sup>☆</sup>



## Riesgos asociados al uso no controlado de la leche materna donada

Nadia Raquel García Lara<sup>a</sup>, Manuela Peña Caballero<sup>b,\*</sup>

<sup>a</sup> Presidenta de la Asociación Española de Bancos de Leche Humana, Servicio de Neonatología, Hospital 12 de Octubre, Banco Regional de Leche Materna de la Comunidad, Madrid, Spain

<sup>b</sup> Vicepresidenta de la Asociación Española de Bancos de Leche Humana, Unidad de Neonatología, Hospital Materno Infantil Virgen de las Nieves, Banco de Leche del Hospital Virgen de las Nieves, Granada, Spain

Human milk has a significant impact on the outcomes of infants born very preterm, with very low birth weights or admitted to hospital as newborns due to disease. When the mother's breast milk is insufficient, the best alternative nutrition is human donor milk (HDM) from carefully selected women.<sup>1</sup> Some of the demonstrated benefits of HDM in preterm newborns include protection against necrotising enterocolitis, improved feeding tolerance, decreased incidence of bronchopulmonary dysplasia, fewer days of catheterisation and parenteral nutrition, increased rate of breastfeeding at discharge and significant reductions in cost. There is also evidence of decreased cardiovascular risk in the long term.<sup>2</sup>

The abundant scientific evidence that supports the benefits and safety of HDM has led to the emergence of milk banks throughout the world, including Spain, since the late XX century. In 2001, the first milk bank in Spain opened in Mallorca,<sup>4</sup> and in 2007, the Hospital 12 de Octubre in Madrid opened the first milk bank integrated in a neonatal care unit. At present,

there are twelve milk banks in ten autonomous communities (Galicia, Asturias, Aragón, Catalonia, Autonomous Community of Valencia, Andalusia, Extremadura, Madrid, Castilla y León and Baleares). Milk banks have not only increased in number, but also expanded the areas they serve, as they distribute HDM to a greater number of hospitals. Thus, in 2009 the number of newborns that benefited from HDM in Spain was 333, compared to nearly 2000 newborns in 2015.

The objective of all milk banks is to offer milk of guaranteed safety and the highest possible quality.

### Risks associated to the unregulated use of donor human milk

The awareness of the benefits of human milk for child health has extended to the general population. Women that cannot produce enough milk for their children increasingly demand breast milk from other mothers. In recent years, we have witnessed a surge in the practice of lactating women selling or donating their milk to women that demand it. This practice has become widespread through social networks and web pages in an uncontrolled manner, facilitated by the lack of legislation regulating this activity.

The Spanish Association of Milk Banks (Asociación Española de Bancos de Leche [AEBLH]) urges us to reflect on

<sup>☆</sup> Please cite this article as: García Lara NR, Peña Caballero M. Riesgos asociados al uso no controlado de la leche materna donada. An Pediatr (Barc). 2017;86:237–239.

\* Corresponding author.

E-mail address: [mapeca06@yahoo.es](mailto:mapeca06@yahoo.es) (M. Peña Caballero).

this habit and to explain the significant consequences that receiving milk from a different mother in an uncontrolled fashion can have on the health of infants. The practice of providing milk from one mother to children other than their own outside the framework of a milk bank is particularly worrisome, especially when this takes place in neonatal units, given the heightened vulnerability of the recipients (very preterm or ill newborns). In this context, every aspect related to safety and quality is of utmost importance.

Human milk is a biological fluid, and thus carries a risk of transmitting infectious diseases from donor to recipient. The infections reported as transmissible through milk include bacterial, viral, parasite and prion infections.<sup>2</sup> Thus, viral diseases caused by HIV, CMV or HTLV, which have a considerable impact on the short- or long-term health of the newborn, can be transmitted through human milk.

Furthermore, milk can be exposed to bacterial contamination during its storage and handling (expression, preservation, storage and transport). Research has shown that there is a higher prevalence of bacterial contamination in breast milk sold over the internet compared to milk given by donors to banks, and also that nearly 10% of it contains some cow's milk added to increase the volume of the milk.<sup>3</sup> Last of all, the studies published to date have identified maternal milk as a potential vehicle for contaminants. Uncontrolled milk donation poses hazards to recipients due to the potential exposure to harmful toxic substances (pesticides, mercury, medicines, drugs or herbs).

The European Milk Bank Association (EMBA) and the Human Milk Bank Association of North America (HMBANA) have issued a joint statement warning of the dangers involved in this practice ([www.europeanmilkbanking.com](http://www.europeanmilkbanking.com)). The AEBLH has endorsed this statement ([www.aebhlh.org](http://www.aebhlh.org)).

The World Health Organization, too, has included three records that evince the risk of harm secondary to consumption of contaminated human milk sold through the Internet in its Notify Project (Global Database of adverse events associated with any form of tissue donation; [www.notifylibrary.org](http://www.notifylibrary.org)).

Although there are no laws that regulate the activity of milk banks, these facilities, aware of the importance of guaranteeing the quality and safety of HDM, have developed their own systems to control the process, and some of them have quality management systems with ISO 9001:2008 certification.<sup>4</sup> Milk is handled following the control systems used in the food industry to minimise bacterial contamination (hazard analysis and critical control points). Donors are subject to a strict selection and monitoring process, and the donated milk to rigorous quality controls before it is accepted.

The selected donors have an interview with a specially trained health professional, including a lifestyle and health habits questionnaire, and must test negative to the following viral and bacterial infections: HIV, hepatitis B and C virus, HTLV and syphilis.

Milk banks refuse donors that use alcohol, tobacco or any type of abused substances. The use of conventional or herbal medicines with potential adverse effects on newborns is also a contraindication for donation.

Milk received in milk banks is frozen until treatment. At the time of reception, the staff verifies that the milk

is stored in an appropriate and intact container, correctly labelled and frozen. Each thawed container is subjected to an initial organoleptic test for colour and aroma. Another quality control is performed later (bacterial culture or measurement of titratable acidity) to discard HDM that is very deteriorated or contaminated.

Adequate milk is subjected to a thermal treatment known as Holder Pasteurisation that destroys all forms of vegetative bacteria, viruses such as HIV, CMV, papillomavirus or Zika virus, and parasites such as *Trypanosoma cruzi*. After pasteurisation, microbiological testing is performed again, and only milk whose samples are free from bacterial growth is considered fit for use. The pasteurised milk is kept frozen.

The temperature during frozen storage and during Holder Pasteurisation are monitored continuously. If there are any deviations from the ranges considered safe, the donated milk must be discarded. The distribution of milk is performed following procedures that ensure proper cold chain management.

Human milk is always dispensed by prescription. The low availability of HDM justifies prioritising its administration to the newborns known to benefit most from it (very preterm, with very low birth weight, or ill).

To date, we have not heard of any infectious adverse effects derived from the use of pasteurised milk distributed by milk banks. The probability of infection is extremely low, given the double controls performed on one hand in donor selection and on the other with the subsequent pasteurisation of donor products.

When it comes to the toxic products that may contaminate milk, the interview with the mother in which she is asked about her lifestyle habits and health condition, combined with the fact that milk bank recipients usually get milk from various donors, make significant exposure to any toxins highly unlikely (newborns would be exposed to insignificant or low-risk concentrations).

## Conclusions

The practice of poorly controlled human milk donation through the Internet or even in hospital settings cannot in any way be considered free of risk for the newborn that receives it and thus must not be accepted.

At present, in the absence of legislation regulating the activity of human milk donation, only human milk banks have controls set up that guarantee the safety of the process. The development of a legal framework could contribute to guaranteeing the safety of human milk donation and facilitate its control.

Last of all, promoting the donation of human milk to established banks would increase the availability of safe HDM for those newborns who, on account of their vulnerability, would benefit most from it.

## References

1. WHO e-Library of Evidence for Nutrition Actions (eLENA). Available from: <http://www.who.int/elena/titles/donormilk-infants/en/index.html#> [accessed January 2015].

2. Arslanoglu S, Corpeleijn W, Moro G, Braegger C, Campoy C, Colomb V, ESPGHAN Committee on Nutrition. Donor human milk for preterm infants: current evidence and research directions. *J Pediatr Gastroenterol Nutr.* 2013;57:535–42.
3. García-Lara NR, García-Algar O, Pallás-Alonso CR. Human milk bank and breastfeeding. *An Pediatr (Barc).* 2012;76:247–9.
4. AAP Committee on Nutrition, AAP section on Breastfeeding, AAP Committee on fetus and newborn. Donor human milk for the high-risk infant: Preparation, safety, and usage options in the United States. *Pediatrics.* 2017;139:e20163440.