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## **Human milk banks: a need for further evidence and guidance**

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## Human milk banks: a need for further evidence and guidance



Human milk is the biological norm for nutrition in infants, with a mother's own milk recognised as the ideal nutritional source for optimal infant health. When a mother's own milk is unavailable, WHO<sup>1</sup> and UNICEF recommend donor human milk as the best alternative for babies with low birthweights. Growing recognition of the benefits of donor human milk has led to increasing global interest in creating and sustaining human milk banks to fulfil the need for donor human milk.

Human milk banks have now been established in over 60 countries globally, with a small but increasing number of milk banks operating in low-income and middle-income countries.<sup>2</sup> This growth has led to calls for equitable access to human milk for vulnerable infants, such as low birthweight babies with necrotising enterocolitis.<sup>3</sup> Despite recommendations for donor human milk and the global expansion of human milk banks, little authoritative guidance exists on the implementation, operation, and regulation of human milk banks. The importance of safe operational guidelines and a coordinating body to collate and communicate data have been highlighted by the milk-banking community and emphasised by the current COVID-19 pandemic.<sup>4</sup>

In response to this need, the Institute of Biomedical Ethics and History of Medicine of the University of Zurich organised an international expert meeting on the need for global guidance for human milk banking, also sponsored by WHO.<sup>5</sup> Although the meeting confirmed the demand for formal guidance among the milk banking community, particularly in low-income and middle-income countries, it also revealed several fundamental issues that need to be addressed.

Human milk is classified differently worldwide, leading to variation in the legal frameworks governing its use and operating procedures. Most commonly, human milk is categorised as a food or nutritional therapy.<sup>6</sup> Unlike other food substances, donor human milk is a biological material derived from the human body and processed with the intention of clinical application. As such, WHO considers it a medical product of human origin.<sup>7</sup> A consensus on the nature of human milk as a regulated substance needs to be agreed upon before deliberation on a unified set of procedures on safe handling and precautions for appropriate use to begin.

The evidence is clear that donor human milk is beneficial to the health of vulnerable infants, particularly for preventing necrotising enterocolitis and improving feeding tolerance.<sup>8</sup> Little evidence exists on the effect of donor human milk on other health issues, including sepsis. The value of donor human milk for healthy term infants is not documented. More evidence is also needed to understand the effect of the different types of handling, processing, or pasteurisation procedures, and fortifications of donor human milk after processing, all of which determine the properties of the resultant milk. This knowledge is necessary to inform guidelines on optimum processing of donor human milk for specific health needs of infants.

There are a multitude of ethical issues around human milk banking, beginning from procurement and extending through to processing, storage, and allocation. Judging how these concerns play out in different cultural and socioeconomic contexts, and identifying the most appropriate policy response, is currently limited by a shortage of studies.

The motivations behind donating human milk remain under-researched. Motivations include expressions of altruism, finding use for excess expressed milk, access to breastfeeding support through participation in human milk donation programmes,<sup>9</sup> and coping with grief after the loss of an infant.<sup>10</sup> Although these donations can sometimes be reimbursed in recognition of the substantial time and effort required to donate human milk, the ability to donate regularly over a period of months could be perceived as a financial opportunity for donors from low-income groups to support their families. The issue of reimbursement is complicated by the operations of for-profit companies selling donor human milk, violating the principles of managing medical products of human origin.<sup>7</sup>

Additionally, providing human milk for monetary compensation could harm donors from low socioeconomic groups who are likely to have poor baseline health and nutrition. The additional lactogenesis puts them at risk for maternal depletion, leading to negative energy balance and nutrient deficiencies. Milk could also be diverted from an infant to meet incentivised demands for donor human milk.

As a medical product of human origin, donor human milk is subject to the principles of universal coverage with equitable access and allocation systems based on clinical criteria and ethical norms.<sup>7</sup> In practice, covering the cost of donor human milk for recipients can present a challenge, especially in countries without universal health coverage. Donor human milk is not always covered by insurance, and families might have to pay for access themselves.

The ready availability of donor human milk from human milk banks could lead to the use of donor human milk as a convenience product at the expense of efforts to support breastfeeding and the provision of a mother's own milk. The priority in clinical settings should always be to support mothers in providing their own milk to their babies. It is important to ensure that resources for supporting breastfeeding are not diverted towards the establishment or running of human milk banks.

The ability to provide human milk to all infants who need it contributes to a health system's ability to achieve health and development commitments relating to human rights, UN Sustainable Development Goals, and targets for maternal, infant, and young child nutrition. At the same time, important technical and ethical issues need to be urgently clarified to minimise the potential of harm.

Building on the important gaps that have been identified, a succinct research agenda will need to be defined that allows us to efficiently produce the evidence that is required to develop robust global guidance on the processes relevant to human milk banking, and the appropriate use of donor human milk.

We declare no competing interests.

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