

Published in final edited form as:

*Lancet Glob Health*. 2019 November 01; 7(11): e1484–e1486. doi:10.1016/S2214-109X(19)30402-4.

## Call to action for equitable access to human milk for vulnerable infants

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Breastfeeding, which is an integral component of human reproduction, prevents the infant mortality associated with alternative feeding methods owing to the unique nutritional and immunoactive properties of human milk.<sup>1</sup> UNICEF and WHO emphasise the crucial role of breastfeeding in addressing the Sustainable Development Goals (SDGs), including improving child nutrition (SDG 2), preventing child mortality and decreasing the risk of non-communicable diseases (SDG 3), and supporting cognitive development and quality education (SDG 4).

Although extensive evidence supports the importance of breastfeeding for infant health and development, many infants worldwide do not have access to breastfeeding or their own mother's milk because of maternal death, illness, or separation. Up to 40% of infants in neonatal intensive care units globally cannot access sufficient mother's milk during the first days or weeks of life.<sup>2</sup> These vulnerable infants—mainly preterm neonates with low birthweight—are at greater risk of morbidity and mortality from severe digestive complications, infections, and delayed growth or development than full-term or healthy infants. For these infants, WHO recommends safe use of donor human milk through human milk banks as a key risk reduction strategy.<sup>3</sup>

To address this need, over 600 human milk banks have been established in more than 60 countries, but most are in Europe, the USA, Asia, and Brazil, with a nationalised system

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of more than 230 human milk banks in Brazil alone.<sup>4</sup> More of these banks are needed. Human milk banks serve a critical role by recruiting milk donors, and collecting, processing, screening, storing, and distributing safe donor human milk. Without ensuring a strong global breastfeeding culture and support system, not all vulnerable infants will have access to donor human milk. Global scale-up of human milk banks has been hampered by the absence of global policies and standards to guide donor programmes. For example, there is no consensus on the classification of human milk as a food, tissue, medicine, or other possible classification for regulatory purposes, which has important implications for how human milk banks are governed and legislated. To date, in most countries, human milk banks are developing operating systems and guidelines without systematic coordination or with limited guidance on global best practices.

There are a number of important ethical considerations that policymakers, regulators, health workers, and mothers must consider in facilitating and navigating supportive breastfeeding environments, including the provision of human milk within different socioeconomic contexts.

Ethical challenges include the commercialisation of donor human milk for profit and exploitation of women in low-income settings selling breastmilk—where detrimental to their own child’s health—for purchase by consumers in high-income settings;<sup>5</sup> managing risks associated with peer-to-peer sharing and selling of unscreened human milk;<sup>6</sup> weighing trade-offs for increasing screening of donors to ensure milk safety with increasing supply to address unmet need;<sup>7</sup> potential risks that donor’s own infants are not optimally breastfed; and determining how best to prioritise provision of donor human milk in times of scarcity.<sup>8</sup> A crucial and overriding challenge is ensuring the appropriate use of donor milk so that it serves as a bridge to support breastfeeding, rather than displacing a mother’s own milk and breastfeeding.<sup>9,10</sup>

To address these challenges, the Ethox Centre of the University of Oxford and PATH convened a working group—the Oxford-PATH Human Milk Working Group—of technical and policy experts in nutrition, human milk banking, human rights, bioethics, and maternal, newborn, and child health to develop ethical guidance in support of safe and equitable access to human milk and breastfeeding for vulnerable infants. Participants shared perspectives from Australia, France, Germany, India, Kenya, Malawi, Mexico, the Philippines, South Africa, UK, USA, and Vietnam. The working group identified cross-cutting ethical considerations and key actions that should be addressed as part of global and regional responses to donor milk policy and guideline development (panel).

The working group calls on global, regional, and country-level policy and regulatory bodies to establish governance mechanisms and enact legislation for the safe and ethical use of donor human milk in a way that also protects, promotes, and supports breastfeeding—similar to the policies established to guide the safe, ethical use of medical products of human origin. These standards and policies are urgently needed to inform the development and operations of donor human milk programmes at the national, regional, and global levels. By heeding this call, we can work together to protect breastfeeding and safe, equitable access to human milk for vulnerable infants, and for all infants and young children globally.

## Acknowledgments

K-IB, KM, and CE report grants from the Family Larsson-Rosenquist Foundation. JC, MP, and MK declare no competing interests. The convening of the working group was supported by a Wellcome Trust Strategic Award (grant number 096527), which supports the activities of the Global Health Bioethics Network, a partnership between the Ethox Centre and the Wellcome Africa and Asia Programmes.

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### **Panel: Ethical considerations to shape key actions**

#### **Ethical considerations**

##### **Vulnerability**

Consider potential medical, social, and economic vulnerabilities of both donor and recipient mother-infant dyad and mechanisms for reducing vulnerabilities.

##### **Equity and fairness**

Consider which populations carry the risks and burdens of supplying donor human milk; and which receive the benefits of donor human milk. Consider how equity and fairness are addressed through allocation and access to donor milk and develop safeguards to prevent exploitation of women donating and selling milk.

##### **Respect for autonomy**

Consider and respect personal and community decisions regarding donor human milk. Consider the role that sociocultural factors, such as religion and kinship, play in decision-making processes.

##### **Human rights**

Ensure equitable access to donor human milk, without discrimination, for infants in need. Call on governments to meet their commitments to women and children through existing conventions and human rights mechanisms,\* which call for maternity protection, gender equality, and rights of women and children to adequate food, nutrition, health, and informed choice.

#### **Global and regional actions to achieve equitable access to human milk**

##### **Action 1**

Ensure that ethical principles of equity and fairness, reduction of vulnerability, and respect for autonomy and human rights shape the development of donor human milk global, regional, and national guidelines and legislation.

##### Steps required

- Promote dialogue among nutrition and maternal lactation stakeholders at global and national levels to examine ethical challenges and proposed solutions to inform areas of future research or areas requiring additional global or national guidance or programmatic support.
- Conduct formative research to identify additional ethical principles and cultural and contextual considerations to shape policy and good practice.

##### **Action 2**

Prioritise donor milk guidance at the global level.

##### Steps required

- Develop global guidance on operational standards that can be incorporated into legislation at the national level for safe and quality human milk banks and appropriate donor human milk use.
- Develop a regulatory framework for establishing policies and legislation to support safe and effective learning from model approaches.

**Action 3**

Prioritise donor milk guidance at regional and national levels.

Steps required

- Develop policies and legislation to protect breastfeeding and appropriate use of donor human milk, learning from model approaches.
- Develop locally appropriate operational standards for safe and high-quality human milk banks.

**Action 4**

Address biomedical and social science research gaps to inform global and national donor human milk strategies.

Steps required

- Conduct formative research to better understand motivations, barriers, and trade-offs for women donating, selling, and sharing their milk and for their infants receiving donor human milk.
- Gather clinical evidence on benefits for breastfeeding of donor human milk and derived products. Conduct operational research to guide national scale-up of human milk banks.

\*Including those outlined by the International Labor Organization, UN human rights and treaty bodies, the UN Human Rights Council, and the UN Economic and Social Council.