assessment for tuberculosis preventive therapy. The provision of tuberculosis preventative therapy must now be viewed as a core and emergency response to COVID-19 for households in which someone has been diagnosed with tuberculosis. Desultory discussions on tuberculosis catch-up plans must be reframed as emergency response interventions, with provision of tuberculosis preventive therapy to all household contacts of persons newly diagnosed with tuberculosis at the core of the mission.

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*Erika Mohr-Holland, Bianca Douglas-Jones, Ivy Apolisi, Noluvo Ngambu, Shaheed Mathee, Rabia Cariem, Vanessa Mudaly, Colin Pfaff, Petros Isaakidis, *Jennifer Furin, Anja Reuter*

jennifer_furin@hms.harvard.edu

Department of Global Health and Social Medicine, Harvard Medical School, Boston, MA 02115, USA (JF); Médecins Sans Frontières, Cape Town, South Africa (EM-H, BD-J, IA, CP, PI, AR); Department of Health, Cape Town, South Africa (NN, SM, RC, VM)

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Making human milk matter: the need for EU regulation

One in ten infants is born preterm worldwide, with an average preterm birth incidence of 8·7% in Europe.[1] Together with sick and low-birthweight infants, preterm babies belong to the most vulnerable group of patients and require special care, including nutrition. The mother's own milk is without doubt the preferred choice for infant feeding,[2] and exclusive breastfeeding during the first 6 months of life is recommended. However, when the mother's own milk is not available, donor milk from a human milk bank is the next best option, because of the undisputed health benefits of human milk.[2,3] Furthermore, donor milk acts as a bridge to breastfeeding, with positive psychological and emotional effects for both mother and child.[2,4]

In Europe, an increasing number of human milk banks provide this urgently needed nutrition.[5] The process of human milk donation is complex, entailing (among other processes) screening and blood testing of donors and processing, preservation, storage, and distribution of donated human milk (appendix p 2). Furthermore, the European Directorate for the Quality of Medicines & HealthCare provides evidence-based recommendations for the establishment and operation of human milk banks.[6]

In view of the unique role and importance of human milk in infant nutrition, it is surprising and problematic that donor human milk (a substance of human origin) and human milk banking are currently unregulated not only at the EU level but also often on a national level.

Legal uncertainty regarding the status and handling of donor human milk provides a disincentive to adopt evidence-based practices about human milk-based nutrition. This uncertainty leads to scant access, concerns about safety, questions about funding and reimbursement, an increased administrative burden, and underutilisation of donor human milk in many neonatal units. These consequences are especially pronounced in countries where human milk bank services are not well established.[7] The current challenges caused by the COVID-19 pandemic make issues related to human milk banking services even more pressing.[8]

The Human Tissues and Cells Directive (2004/23/EC), which currently does not include donor human milk, was

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See **Online** for appendix

Panel: **Call to action**

We call on European policy makers to ensure that any revision of the Human Tissues and Cells Directive:

- Recognises human milk as the best option for preterm, sick, and low-birthweight infants and has, at its core, the theme of ensuring a safe secure supply for all mothers in need of milk for their infants. The mother's own milk is the first choice in infant feeding. When the mother's own milk is not available, donor milk from a human milk bank is the preferred option.
- Includes a delegated act on donor human milk to be developed in close cooperation with key stakeholders in infant care and human milk safety.
- Ensures equitable access to safe donor human milk for preterm, sick, and low-birthweight infants, as a key theme of the legislation, and accounts for the practical specifics of human milk donation.
- Endorses recognition, support, and regulation of human milk banks in Europe.
- Includes the need for EU-wide research and data collection for human milk donation and use.

adopted by the European Parliament and Council in 2004 and is about to be revised.[9] The first formal evaluation of the Directive represents a unique opportunity to fill the legislative vacuum at the EU level and to improve access to donor human milk.

Building on this momentum, we formed an international working group—the European Foundation for the Care of Newborn Infants (EFCNI) Working Group on Human Milk Regulation—to advocate for the inclusion of donor human milk in the Human Tissues and Cells Directive. For the first time, international and interdisciplinary experts in the field of human milk, including patient representative groups, have come together during two digital roundtable discussions in May and June, 2020, to jointly develop policy recommendations on the need for regulation of donor human milk. The recommendations of the working group were launched during a digital policy workshop hosted by Members of the European Parliament on Nov 18, 2020.[10] The document calls on European policy makers to include donor human milk in the Human Tissues and Cells Directive, considering the special nutritional and biological characteristics of the substance (panel).[10]

Extending the scope of EU legislation to donor human milk would ensure that the process of human milk donation meets high safety and quality standards and would allow for better coordination within and across countries to ensure equitable access to safe donor human milk. Regulation, however, must take a facilitating role, and potential increases in costs and administrative workload must be avoided so as not to endanger a smooth donation process and the running and set-up of milk banks.

The EFCNI Working Group on Human Milk Regulation advocates the need for regulation of donor human milk and human milk banking in Europe to make sure that the specific medical and nutritional needs of newborn babies—particularly preterm, sick, and low-birthweight infants—are met. Providing the best care possible, including nutrition, will not only relieve the pressure from already challenged health-care systems in Europe but also save lives and improve the quality of life of the youngest members of society. Providing high-risk neonates with safe and secure human milk must, therefore, be considered a public health priority and a human right for all newborn babies.

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**Johanna Kostenzer, on behalf of the EFCNI Working Group on Human Milk Regulation*
johanna.kostenzer@efcni.org

European Foundation for the Care of Newborn Infants, 81379 Munich, Germany

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