

# Ensuring Safety in Donor Human Milk Banking in Neonatal Intensive Care



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## KEYWORDS

• Donor human milk banking • Guidelines • Best practice

## KEY POINTS

- There is a significant variation in practice in human milk banking across jurisdictions.
- A single international standard of practice is not possible and there are currently few methods to assess appropriate milk-banking practice.
- Milk banks must assess both clinical responsibility and social responsibility to both their donors and recipients.
- Universal hazards and benefits should be defined by donor human milk-banking services using a systematic method.
- Local jurisdictions will need to assess these benefits and hazards using existing and internationally recognized hazard assessment tools.

## INTRODUCTION

At its most basic definition, a donor human milk bank can be considered to be “a store of donated human milk for later use when required.” This definition is simplistic but useful, as it is one of the few available that covers the diverse range of milk-banking practices. It implies that any donor human milk-banking service (DHMBS) will engage in a process of selection of donors, storage, and/or processing of product and will then dispense that product to appropriate recipients. Within each of

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these basic functions, practice in milk banking varies across and even within jurisdictions.<sup>1</sup> The result is that there are now various definitions of an appropriate donor; a range of collection, storage, and processing practices; and a range of recipients of donor milk products.<sup>1-6</sup> This presents a difficulty for new human milk-banking projects and when assessing appropriate DHMBS practice. There is growing availability of donor milk in the neonatal intensive care unit (NICU) and for the vulnerable patient it is desirable to standardize practice to ensure DHMBSs are providing a safe and credible clinical service. In addition, where donor human milk product itself may cross borders (be that one hospital to another or geographic borders), it is desirable to ensure a uniform standard of safety in donor human milks. The recent development of an ISBT128 standard for donor human milk labeling has been an important step in this process.<sup>7</sup> Recent editorials<sup>8</sup> rightly question the unregulated expansion of donor human milk banking with limited evidence for the benefit of donor milk in NICU. DHMBSs must adequately respond to these concerns. There is also a growing interest in the community toward informal sharing of breast milk.<sup>9</sup> This practice is often confused with formal human milk banking in the NICU, whereas it is clear they are very different public health issues and should be considered separately. However, DHMBSs in some jurisdictions do provide a service to both NICU patients and the general community.<sup>9</sup> A clear description of the wide range of considerations for safe and ethical milk-banking practice in the NICU may assist parents, policy makers, and clinicians requiring an objective measure of a minimum acceptable standard of safety when sharing breast milk.

This article aims to develop a potential framework to design and assess appropriate milk-banking practice to ensure safety. The principles that were used to establish safe donor human milk banking in Perth, Western Australia, where contemporary human milk banking began in 2006,<sup>3</sup> are defined. Although discussion focuses on the activity of a DHMBS in an Australian NICU, these general principles may serve as a foundation to assess appropriate milk-banking practices in any setting. This article does not recommend a single standard of practice in donor human milk banking or suggest that the practices used at the PREM (Perron Rotary Express Mothers) Milk Bank represent the only safe practice in milk banking. However, the potential hazards and benefits of donor human milk banking are universal and can be defined. By identifying these initial principles of donor human milk-banking practice, DHMBSs can design appropriate processes, or assess and validate existing practice with reference to the intended recipient and with consideration to local issues. The approach outlined in this article is developed with the intention of assessing and validating our own practice, its publication is intended to ensure transparency of our service and provide opportunity for objective criticism. This recognizes an unresolved issue for DHMBS internationally, current services have evolved different practices based on historical experience and local risk factors. This has resulted in significant variation in the practice of human milk banking around the world.

## **RESPONSIBILITIES OF A DONOR HUMAN MILK-BANKING SERVICE**

The guidelines for donor blood services are useful when considering responsibilities for DHMBSs, as there are similarities between these services. The World Health Organization<sup>10</sup> considers the primary responsibility of blood transfusion services “to provide a safe, sufficient and timely supply of blood and blood products.” Furthermore, they suggest all prospective blood donors be assessed for their suitability to donate, and that the purpose of this assessment is to

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