

## **The Known's and Unknowns of Donor Human Milk Banking**

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The Human Milk Bank at KEMH has been providing pasteurised donor human milk (PDHM) to very preterm for the past 4.5 years. It is the first human milk bank (HMB) to operate in Australia in over 20 years. Our community has rapidly embraced the concept of human milk banking, with both donations and demand for PDHM exceeding expectations. We now provide almost 1000 litres of PDHM each year to over 300 patients of our hospital. Providing PDHM in 'exceptional circumstances' where a mothers' own milk is unavailable is supported by the WHO and UNICEF. We submit that neonatal intensive care is an exceptional circumstance. Although evidence supporting PDHM use from randomised control trial (RCT) is limited, the latest systematic reviews suggest a lower risk of necrotising enterocolitis with PDHM as opposed to artificial formula. Study design and ethical issues may limit future evidence from RCT. We therefore support the ongoing use of PDHM in neonatal care, where provided by an appropriately managed HMB. Internationally many HMBs operate unregulated, and currently this is also the case in Australia. To ensure safety our HMB has committed to meet the appropriate standards recommended in the Code of Good Manufacturing Practices (Blood and Tissues) in Australia and models risk management during processing on Codex HACCP (Hazard Analysis Critical Control Point) requirements. We know that milk banking is accepted by the community but also that the demand may exceed the evidence base for which we provide PDHM. Beyond reducing the risk of NEC in preterm infants there is little evidence in the literature for benefits from PDHM. We also know that current processing methods produce a safe product, but potentially undesirable reduction in product quality. These areas, among others warrant further research attention by human milk banks. There is scope to continually re-evaluate the screening of donors and quality standards recommended during HMB. This will be most effective if strong networks of HMBs are developed with regional reference laboratories to encourage compliance with safety guidelines. HMB networks will facilitate collection of evidence for refining HMB practice and improving outcomes for preterm and sick infants.