

MINI REVIEW

Review highlights the importance of donor human milk being available for very low birth weight infants

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Abstract

Aim: The aim of this paper was to review the role that donor human milk plays in caring for very low birth weight (VLBW) infants.

Methods: This review focussed on academic papers and background information published in English and French up to 8 August 2021.

Results: Donor human milk provides a useful bridge to successful breastfeeding in hospitalised neonates and does not have a negative impact on the use of mother's own milk and breastfeeding rates at discharge. It helps to prevent key complications of prematurity, particularly necrotising enterocolitis up to 36 weeks of postmenstrual age, which is more common in infants fed formulas based on cows' milk. When it is carefully fortified, it supports the postnatal growth of the majority of very preterm infants. Well-organised, accessible human milk banks are required to cover the needs of hospitalised infants, and donor human milk must be prioritised for patients who derive the greatest health benefit from it. These include very preterm infants and those born at term, or near term, with surgical digestive malformations or congenital heart disease.

Conclusion: Safe, high-quality donor human milk, which is distributed by well-organised human milk banks, is essential for the most vulnerable hospitalised neonates.

KEYWORDS

breastfeeding, congenital heart disease, digestive malformations, necrotising enterocolitis, prematurity

1 | INTRODUCTION

One of the key roles of neonatal units is to support the growth and development of preterm infants during the critical period between birth and term equivalent age. Nutritional care is an important part in this process, as it is crucial that these vulnerable babies receive sufficient nutrients. Human milk makes a major contribution to this goal. It also has an indirect effect on growth and development, by alleviating the risk of complications due to premature birth.¹

Mother's own milk is the first choice for preterm infants, but some mothers find it difficult to produce and sustain enough milk to meet their infants' needs. A survey of 11 European countries showed that, on average, only 58% of very low birth weight (VLBW) infants received any breast milk at discharge and the rates ranged from 36% to 80%.² Donor human milk should be the second choice in such cases, as this provides VLBW infants with essential nutritional and bioactive components. It also minimises their exposure to cows' milk formulas, which have been associated with an increased risk of necrotising enterocolitis (NEC).³

Abbreviations: NEC, necrotising enterocolitis; RCT, randomised controlled trial; VLBW, very low birth weight.

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This review focussed on academic papers and background information published in English and French up to 8 August 2021. It discusses the issues related to using donor human milk in neonatal units and its relevance for high-risk infants. It looks at the definition of donor human milk and whether it provides VLBW infants with significant health benefits. The review also looks at what impact treating donor human milk has on the properties of the milk and whether it meets the nutritional needs of high-risk neonates. Finally, it examines the need for donor human milk in neonatal units and how human milk banks are organised to ensure that donor human milk is made available.

2 | HOW DONOR HUMAN MILK IS DEFINED

Donor human milk is defined in this review as milk that is collected from an established human milk bank under strict hygienic conditions. The milk comes from donors who are selected following health screening and serological blood tests. It is microbiologically controlled, transported and stored at the right temperature, pasteurised and distributed under strict tracking conditions.⁴ It does not include unpasteurised milk and sharing human milk via direct or Internet-based routes, as these do not meet the same safety levels and are not recommended.⁵

Donor human milk has a different legal status in some countries. For example, it is a food product in the United States, a health product of human origin in France and a medical product in others. Many countries do not have strict regulations or any national regulations at all. Some have recommendations that are based on a national consensus by healthcare professionals and other countries have a total lack of harmonisation. This explains the variations in how human milk banks function between different countries. To our knowledge, France and Italy are the only countries that provide specific directives that are enshrined in law, and these include strict regular audits, which are carried out by national health authorities. The European Milk Bank Association issued its recommendations in 2019.^{4,6} In the same year, a new chapter on donor human milk was included in the fourth edition of the *Guide to the quality and safety of tissues and cells for human application*, published by the European Directorate for the Quality of Medicines & HealthCare.⁷ This European document states that donor human milk is a health product.

To summarise, good-quality donor human milk needs to be distributed by established human milk banks to ensure its safe inclusion in the nutritional management of hospitalised neonates.

3 | DOES IT PROVIDE VLBW INFANTS WITH SIGNIFICANT HEALTH BENEFITS?

It is hard to tell what effect donor human milk has on the health and development of VLBW infants for two reasons. First, studies do not always specify the type of human milk that infants receive. Second, most studies use donor human milk or formulas to supplement the

Key Notes

- This review shows that donor human milk provides a useful bridge to successful breastfeeding in hospitalised neonates, with no negative impact on the use of mother's own milk and breastfeeding rates at discharge.
- It helps to prevent key complications of prematurity, particularly necrotising enterocolitis up to 36 weeks of postmenstrual age.
- Priority must be given to very preterm infants and those with surgical digestive malformations or congenital heart disease.

mother's own milk and not to provide an exclusive diet. It is not ethically acceptable to withhold a mother's own milk, if this is available.

The only randomised controlled trial (RCT) that has evaluated the effect of pasteurisation on neonatal outcomes in VLBW infants is Cossey et al.⁸ They studied 303 infants who received raw or pasteurised mother's own milk during the first 8 weeks of life. There was no difference in the primary outcome of proven late-onset sepsis between the groups. However, a significant dose-response relationship was found between the quantity of enteral feeding and the risk of late-onset sepsis, regardless of the type of feeding. Other outcomes were similar in both groups: weight gain, digestive tolerance, NEC grade 2, bronchopulmonary dysplasia, retinopathy of prematurity and length of hospital stay. This study suggested that pasteurisation did not have any negative impact on short-term clinical outcomes.

The Cossey et al study⁸ was included in a systematic review by Miller et al on the effect of human milk on morbidity in VLBW infants.¹ Published in 2018, it comprised 6 randomised trials and more than 30 observational studies published from 1998 to 2017. The review found that human milk provided a protective effect against NEC and a possible reduction in late-onset sepsis, severe retinopathy of prematurity and severe NEC. There was no conclusive evidence for bronchopulmonary dysplasia.¹ The Cossey et al⁸ RCT, and six observational studies, were analysed to specifically compare unpasteurised and pasteurised human milk.¹ There was no conclusive evidence that pasteurising human milk had any effect on the main clinical outcomes in VLBW infants.

In 2019, Quigley et al's updated meta-analysis reported the effects of feeding VLBW infants with fortified formula, rather than donor human milk, when the mother's own milk was not available. Using formula was associated with higher growth velocity. However, it increased the risk of developing NEC, compared with donor human milk (9.1% versus 5.5%), by a relative risk (RR) of 1.64, with a 95% confidence interval (CI) of 1.03–2.61.³ Silano et al's meta-analysis of four RCTs, which comprised 953 subjects, found that donor human milk did not exert a clear protective effect on surgical NEC when it was compared with formula (RR: 0.45, 95% CI: 0.19–1.09).⁹ Yang et al¹⁰ performed a meta-analysis of 4

RCTs and 8 observational studies, with a total of 3221 subjects. Donor human milk had no impact on the length of hospital stay, compared with preterm formula, but it generally halved the incidence of NEC and the high-quality RCTs reported an overall reduction of 68%.¹⁰

The best way to manage enteral nutrition in infants recovering from uncomplicated NEC, or surgical NEC requiring a bowel resection, is still a matter of debate. However, mother's own milk or donor human milk provide the best enteral nutrition. This is because they contain components such as growth factors, promote gut adaptation and help to digest nutrients.¹¹ If human milk is not available, a cows' milk formula may be used. A high-calorie preterm formula should be the first choice for preterm infants with uncomplicated NEC. Extensively hydrolysed formula, which is not nutritionally adapted for preterm infants, could be used if a cows' milk allergy is suspected, as this is a common risk factor for recurrent NEC. These formulas are often used for infants recovering from NEC because they are thought to help them digest nutrients. However, there is no evidence to support this practice, even after surgical NEC. It has been shown that the protein absorption rate is intact after surgery, and that preterm infants still demonstrate rapid digestion after an intestinal resection.¹² Mother's own milk or donor human milk are the best way to support this process.

To summarise, donor human milk provides a clear protective effect against NEC compared with preterm formula. Despite limited research on this subject, donor human milk is likely to have the same protective effect as mother's own milk against NEC. However, there is no evidence of a similar effect for surgical NEC. The lack of high-quality studies means that there is no conclusive evidence about the impact of donor human milk on late-onset sepsis, retinopathy of prematurity or bronchopulmonary dysplasia.

4 | WHAT IMPACT DOES PASTEURISATION HAVE ON MILK PROPERTIES?

The most widely used method to pasteurise donor human milk is a low temperature for a long time. This is often called Holder pasteurisation, after the device that is used to heat the milk. It is the most feasible method for human milk banks, and it currently offers the best compromise between microbiological safety and preserving the nutrients and immunological components of the milk. The effects of Holder pasteurisation on the immunological components of the milk are more important than the nutritional components (Table 1).¹³ Overall, donor human milk retains significant nutritional and anti-infectious properties. New techniques for pasteurising donor human milk have been suggested, such as using high temperatures for a short time, high-pressure pasteurisation, ultraviolet irradiation and ultrasound.⁶ It is notable that these techniques have mostly been tested by research studies under laboratory conditions, using small amounts of milk.⁶ This is because they are quite expensive, not yet fully available and not

suitable for treating large quantities of donor human milk. Some of these techniques will be available for human milk banks in coming years. In the meantime, it is essential to perform high-quality Holder pasteurisation, which reduces the negative effects of pasteurisation on the immunological components of milk.¹⁴ It is also very important that the equipment that is being used is carefully checked at least once a year and after any routine maintenance or repairs.^{6,13,14}

To summarise, when donor human milk is treated carefully, it retains significant properties that provide good nutrition and help infants to boost their immune systems. It is essential to use high-quality Holder pasteurisation to treat the milk. This currently provides the best compromise between microbiological safety, preserving the main components of milk and enabling milk banks to provide a feasible supply of human donor milk.

5 | CAN DONOR HUMAN MILK MEET THE NUTRITIONAL NEEDS OF HIGH-RISK NEONATES?

In order to answer this question, we need to explore the composition of donor human milk and adapted fortification. While the composition of breast milk is perfectly suited to the nutritional needs of healthy term infants, it does not meet the higher needs of VLBW infants, even when they receive up to 200 ml/kg/day.¹⁵ A meta-analysis by Gidrewicz and Fenton¹⁶ studied the composition of human milk in mothers who delivered preterm or term-born babies. The main difference was the protein content, which was slightly higher in preterm milk than term-born milk during the first weeks. It found more similarities than differences between the two sets of samples. However, the protein content showed similar decreases with postnatal age.¹⁶

Fortifying breast milk is essential and has become standard care in neonatology.^{14,17} This helps to reduce the risk of nutritional deficiencies, including the risk of postnatal growth restrictions or osteopenia.¹⁷ There is no broad consensus on the best way to fortify breast milk, due to the low number of randomised studies. Standardised fortification involves adding a fixed amount of multicomponent fortifier to human milk. New liquid and improved powdered cows' milk-based fortifiers can help infants to achieve adequate growth rates.^{18,19} Liquid human milk-based fortifiers also support the population-based postnatal growth rates that preterm infants would have achieved if they had not been born early.²⁰ Nevertheless, standardised fortification does not suit a significant proportion of VLBW infants. This is because the nutritional value of human milk can be lower than assumed or because an infant's individual requirements are particularly high. This can happen if they are born small for gestational age or with an extremely low birth weight or they have an underlying illness.^{21,22} Individualised fortification involves adding modular fortifiers to increase the protein and energy provided by basic human milk. This is done, so that it reaches its targeted fortification,

NUTRITION, DIGESTION, GUT MATURATION
Total protein content
Bioactive peptides
Total fat
Free fatty acids
Lactose
Electrolytes and minerals
Vitamins E, B2, B3, B5, B12, Biotin
Vitamins A, C, D, B6
Zinc, Copper, Iron
Amylase
Bile salt-stimulated lipase, Lipoprotein lipase, Alkaline phosphatase
Growth factors EGF, TGF-β1-2, GM-CSF
Growth factors EPO, HB-EGF, IGF-1, IGF-BP2~3
Insuline, Leptine, Adiponectine
Osmolality
IMMUNITY, ANTI-INFECTIVE PROPERTIES
Oligosaccharides
Cytokines IL-2, -4, -5, -8, -12, -13, -17
Cytokines IL-7 *
Cytokines IL-1β, -6, -10, TNFα, INFγ *
Lactoferrin *
Lysozyme and Lysozyme activity
IgA, IgAs, IgG, IgG4
IgM *

Preserved (or slightly reduced)
Reduced
Reduced or Suppressed
Suppressed
Increased

TABLE 1 Effect of low-temperature long-time pasteurization (so-called “holder”) on components contributing to nutritional quality and anti-infective properties of human milk

* Discordant results or wide variation of estimated impact

IL, interleukine; TNF, tumor necrosis factor; Ig, immunoglobulins, EGF, epidermal growth factor; TGF, transforming growth factor.

Abbreviations: EGF, epidermal growth factor; Ig, immunoglobulins; IL, interleukin; TGF, transforming growth factor; TNF, tumor necrosis factor.

* Discordant results or wide variation of estimated impact

namely the best milk composition, or its adjustable fortification, by adjusting the protein status by estimating blood urea nitrogen. Both adjustable and targeted fortification support better postnatal growth than standardised fortification.¹⁵ Adjustable fortification requires accurately monitoring serum urea and weight gain, so that levels can be rapidly changed, in order to avoid growth faltering. Targeted fortification requires accurately measuring the protein and energy content of the basic human milk, but this requires calibrated devices and needs dedicated staff to handle the significant workload.

To summarise, there is no evidence to support the idea that a specific fortification strategy is needed when VLBW infants are fed donor human milk, exclusively or to supplement their mother's own milk. However, as the composition of donor human milk may be slightly different from mother's own milk, individual adjustable or targeted fortification is preferable to standardised fortification.¹⁵

6 | POSTNATAL GROWTH OF PRETERM INFANTS FED DONOR HUMAN MILK

Human milk contains nutrients and bioactive factors that play a role in postnatal growth, namely growth factors, hormones and oligosaccharides. Some of these components are reduced, and more rarely completely destroyed, after Holder pasteurisation (Table 1).¹³ A number of studies have raised concerns about the postnatal growth of VLBW infants fed donor human milk, but RCTs are scarce. Furthermore, some studies have evaluated the different uses of donor human milk during various periods, but most of these only used standardised fortification. Variations in protein content were not taken in account when standardised fortification was used, which explains the lower growth rate reported by some studies when VLBW infants were fed donor human milk. Furthermore, the older fortifiers that were used had suboptimal composition.²³ A single-centre, retrospective study used mother's own milk or donor human

milk supplemented with targeted fortification to provide VLBW infants with a similar protein and energy intake. The authors reported a slightly, but significantly higher, weight gain in those who receive their mother's own milk.²⁴ However, infants fed their mother's own milk or donor human milk both achieved the expected weight gain of between 18 and 20 g/kg/day.¹⁵

To summarise, when donor human milk is used properly, with individual fortification, it supports appropriate postnatal growth in VLBW infants.

7 | WHAT ARE THE TRUE NEEDS FOR DONOR HUMAN MILK IN NEONATAL UNITS?

The donor human milk needs of neonatal units also depend on how they define the infants who must receive it. Most neonatal units that have access to donor human milk provide it until the mother can meet the needs of her infant. The main indication for this extra supply is to provide a bridge to successful breastfeeding. If the volume of the mother's milk is not adequate, donor human milk is commonly continued until the infant has reached either a weight of 1500 g or 34 weeks of postconceptional age.⁵ Most units then switch to a preterm formula if the mother's own milk is not yet available. This strategy, which is dictated by a lack of donor human milk, does not protect infants against the risk of NEC, which can persist until 36 weeks of gestational age.²⁵ The expression of toll-like receptor 4 in the newborn infant's intestine, which is involved in pathogenesis of NEC, rises during development and peaks at 34–36 weeks.²⁶ Reductions in NEC, related to the use of human milk, have been shown to be dose-dependent, so receiving donor human milk is better than formula.¹ Ideally, all VLBW infants should receive their mother's own milk and/or donor human milk until just before they are discharged. However, they consume more milk as they get older, and it can be difficult for milk banks to provide enough donor human milk. Therefore, it seems reasonable to feed VLBW infants until they reach 36 weeks or 1800 g.

Donor human milk is important. However, it is essential to prioritise the indications for its use, to ensure that it meets the needs of VLBW infants and infants born at term or near term with surgical digestive malformations or congenital heart disease.^{3,27} Some human milk banks provide donor human milk to supplement mother's own milk when a woman has delivered a health-term baby but has insufficient lactation. It can also be provided exclusively when there is a medical reason why a woman should not breastfeed.²⁸ However, there are only a few published studies on these less widespread practices. This is because human milk banks already struggle to cover all the needs of VLBW infants, and this vulnerable group seems to get the most significant health benefits from donor human milk. Finally, donor human milk is expensive because it must cover the costs involved in screening donors, laboratory testing their blood and milk, and processing the milk, supplies and transport costs. However, these costs could be considered lower than many

other interventions in neonatal units and one benefit is avoiding NEC cases. The price of donor human milk can be an obstacle in some countries and medical insurance systems do not always reimburse mothers for the cost. For example, insufficient lactation does not meet the reimbursement criterion that donor human milk must be medically indicated.

It is important to strictly prioritise the indications for the use of donor human milk and provide effective support for breastfeeding mothers who give birth prematurely.

To summarise, there is a great need for donor human milk, and human milk banks can struggle to meet that demand. That is why patients who will derive the greatest health benefits must be prioritised. These include VLBW infants and newborn infants, at term or near term, who have surgical digestive malformations or congenital heart disease.

8 | HOW HUMAN MILK BANKS NEED TO BE ORGANISED TO PROVIDE DONOR HUMAN MILK

Human milk banks should be located and organised, so that they are accessible to hospitals who need donor human milk. There are currently more than 500 human milk banks throughout the world, according to the Human Milk Bank Global Map website. For example, North America has 31 not-for-profit human milk banks and some commercial milk banks, but the limited availability and affordability of donor human milk in that region has been highlighted.⁵ In 2014, 65% of UK neonatal units said that the cost of donor human milk was a key limiting factor and 49% cited access.²⁹ France has 34 human milk banks: 15 are in hospitals and are only used for their own patients and 19 are regional, including one that freeze-dries pasteurised milk. This milk has the same qualities as pasteurised milk, but it can be stored at room temperature for 18 months, making it easier to transport and store. It is used to support French overseas territories and other French milk banks when supplies run low. However, France is unable to completely or consistently meet the needs of more than 10 000 VLBW infants born each year.

The requirements for donor human milk and human milk banks are determined by how many mothers choose to feed their babies in hospital and these vary greatly between neonatal units and geographical areas.² It has been well demonstrated that the presence of human milk banks does not interfere with the use of mother's own milk for hospitalised VLBW infants. In addition, it does not reduce the rate of breastfeeding on discharge, but it does decrease formula feeding during neonatal intensive care unit stays.³⁰

To summarise, well-organised, national human milk bank networks are required to cover the needs of hospitalised neonates. The number has been increasing quickly but is still not sufficient to cover the needs of all hospitalised neonates who need donor human milk. This and other recommendations are summarised in [Table 2](#).

TABLE 2 Future steps needed to optimise the use of human donor milk

- Harmonise the global definition of donor human milk and regulate its use
- Carry out research studies to assess the short-term and long-term benefits of using donor human milk
- Establish a clear consensus on which neonates should be given priority, especially when supplies are limited
- Improve the nutritional value of donor human milk, by improving fortifiers and fortification strategies
- Raise awareness of the effects that donor human milk has on the gut microbiota of recipients, the microbiological composition of donor human milk and the use of additives, such as human milk oligosaccharides
- Optimise the treatment of donor human milk, to overcome the side effects of pasteurisation, and validate new treatment techniques, so that they can be used by human milk banks
- Ensure that hospitals have easy access to well-located human milk banks, by expanding global provision

9 | CONCLUSION

Donor human milk is essential for hospitalised neonates, as it provide a bridge to successful breastfeeding. Its properties help to avoid postnatal growth deficits and provide health benefits, despite its handling and treatment by human milk banks. Donor human milk also reduces the need for formula, which is a well-known risk factor for NEC. The use of donor human milk is quickly expanding across the world, and there is a need for harmonised practices. These should be based on evidence from further high-quality studies on the properties of donor human milk and its effects on the health of hospitalised neonates.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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