

REGULAR ARTICLE

Cost analysis showed that feeding preterm infants with donor human milk was significantly more expensive than mother's milk or formula

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Abstract

Aim: This study analysed the comparative cost of feeding donor human milk to preterm infants compared to mother's own milk and formula.

Methods: A document and process analysis and a time measurement study were carried out at the milk bank of the Level 1 Perinatal Center of the University Hospital of Greifswald, Germany, from April to June 2017. The cost analysis data were provided by the University's financial department.

Results: The total cost per year was €92 085.02 for 300 litres of donor human milk: 27% of this was material costs, 51% was personnel costs, and 22% was other overheads. The average cost per litre was €306.95, and staff time was 492 minutes per litre. The total marginal cost for each additional litre of donor human milk, formula or unpasteurised mother's milk was €82.88, €10.28 and €38.42, respectively. Pasteurising a litre of donor milk cost €3.51.

Conclusion: Providing preterm infants with donor milk was much more expensive than using formula or mother's own milk, but the cost of pasteurisation was minimal.

KEYWORDS

cost analysis, donor human milk, maternal breast milk, milk bank, preterm infant

1 | INTRODUCTION

Maternal breast milk lowers the incidence of severe complications of preterm birth, such as necrotising enterocolitis (NEC),¹ retinopathy of prematurity (ROP)² and nosocomial infections³ compared with artificial formula.

A study of 1422 very low birth weight (VLBW) infants from the German Neonatal Network showed that exclusively feeding infants

maternal breast milk was associated with a reduced risk for NEC of a factor of 12.6, for ROP, it was 1.8 and for bronchopulmonary dysplasia, (BPD) it was 2.6.⁴ However, this study also showed that the proportion of exclusively breastfed infants was low, at 15.6%.⁴ Other studies have showed that acute complications were associated with impaired psychomotor development and that reducing these improved long-term outcomes.⁵ In addition, feeding preterm infants with maternal breast milk has been associated with better neurodevelopment.^{6,7}

Abbreviations: VLBW, very low birth weight infants; BPD, bronchopulmonary dysplasia; NEC, necrotising enterocolitis; ROP, retinopathy of prematurity.

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Two strategies exist for increasing the breastfeeding rate. First, feeding infants with their mother's own milk should be promoted.⁸ Second, the European Society for Pediatric Gastroenterology and Nutrition recommends using donor human milk when milk from the infant's own mother is not available.⁹ A Cochrane analysis showed that feeding donor human milk reduced the risk of NEC by nearly two-thirds compared with formula feeding.¹⁰ Another study showed that feeding donor human milk may also reduce the risk of BPD.¹¹

Donor human milk is usually pasteurised before use, to eliminate most bacterial pathogens and transmission of the human immunodeficiency virus and cytomegalovirus.^{12,13} Donor human milk was pasteurised in all but one trial included in the Cochrane Review.¹⁰ However, pasteurisation also reduces milk quality, especially by affecting the immunological properties.^{13,14} Therefore, based on promising experiences in Norway, our hospital uses non pasteurised donor human milk.¹⁵

A survey of donor human milk use in neonatal units in the United Kingdom found that the most commonly reported limiting factor for those not using donor human milk was cost.¹⁶ Despite the fact that feeding donor human milk reduces severe complications in VLBW infants, milk banks are not financed by the health insurance provision that supplements Government funding in Germany. The number of neonatal centres taking care of VLBW infants in Germany is 213 and that is 10 times higher than the number of milk banks, according to the European Milk Bank Association.¹⁷ The aim of this study was to conduct a cost analysis for feeding donor human milk to VLBW infants, as this had not previously been carried out in Germany.

2 | METHODS

The survey took place in the Greifswald Perinatal Center of the Department of Neonatology and Pediatric Intensive Care Medicine, University Hospital of Greifswald, from April to June 2017. The mean number of VLBW infants treated during the 2008-2017 study period was 44 per year. In the last year of the study, 2017, the unit cared for 290 neonatal patients, ranging from 43 VLBWI infants to ill full-term infants.

If it is not possible to feed premature babies with breast milk, the second preference according to the Greifswald Women's Milk Bank Guidelines is donor human milk. It is administered at a birth weight of less than 1000 g or in growth-retarded premature infants born at less than 1500 g. The goal is targeted nutritional rehabilitation, for example in cases of miscolonisation, after surgery on the gastrointestinal tract and in short bowel syndrome.

The donation and administration of breast milk is regulated by internal standard operating procedures.¹⁸ There are currently no national legal regulations for donor human milk in Germany, and it is only defined as a food in three of the 16 German federal states. The donor milk comes mainly from women who also have preterm babies in the unit.

Key notes

- We analysed the cost of feeding donor human milk to preterm infants, compared to mother's own milk and formula.
- The annual cost was €92 085.02 for 300 litres of donor human milk: 27% of this was material costs, and the remainder was personnel costs and overheads.
- Donor milk cost €14.34 per infant per day of care, which was €12.56 more than formula and €7.69 more than unpasteurised own mother's milk.

2.1 | Exclusion criteria for milk donation

Milk donors are temporarily excluded if they acutely ill or they are receiving live vaccinations or other medication. They are

TABLE 1 Fixed and variable costs of donated milk

Cost type	Cost category	Costs per year in Euro
Fixed	Administration	4983.52
	Labour costs-milk kitchen/ milk bank	46 939.20
	Cleaning	1404.23
	Laundry	280.80
	Water	2082.01
	Electricity	274.56
	Heating	1075.34
	Depreciation, service and repair	10 181.36
		Costs per litre in Euro
Variable	Bottles	2.27
	Pump sets	24.45
	Protective clothing	1.89
	Disinfection	8.16
	Aqua	0.16
	MacConkey Agar	1.76
	Caso blood agar	1.68
	Inoculating loop	2.56
	Vacutainer	0.32
	Withdrawal unit	0.08
	Non-departmental services-central laboratory, Microbiology-IHEM:	6.15
Itemised costs	7.00	
Labour costs	26.40	

Note: IHEM Institute of Hygiene and Environmental Medicine.

permanently excluded if they are on long-term medication, have chronic or systemic diseases, have galactosemia or have been lactating for more than 6 months. We also exclude women who are abusing drugs or regularly drink or use tobacco or have an increased risk of sexually transmitted diseases. Women are also excluded if they have tattoos, permanent makeup or piercings or have undergone preservation of blood products within the last six months. Excessive caffeine intake and vegan diets are also part of the exclusion criteria. The donor must be negative for primate T-lymphotropic virus 1, the human immunodeficiency virus, the hepatitis C virus, the hepatitis B virus, syphilis and the cytomegalovirus. They must also have alanine aminotransferase and aspartate aminotransferase values in the normal range. Blood is re-examined after two and six months to detect late seroconversion. The milk is pasteurised if the donors have positive cytomegalovirus immunoglobulin G antibodies and negative cytomegalovirus immunoglobulin M antibodies.

When determining the difference in cost between raw and pasteurised donated breast milk, it should be noted that our Milk Bank Guideline requires that every bottle of donated breast milk must be microbiologically tested before use. Any pasteurised milk is tested after germination and is only suitable if germs fall below a certain level. According to our guidelines, the general pasteurisation of donated breast milk saves very little money compared to feeding raw milk. Pasteurisation costs €3.51 per litre with no additional administration costs. This costs include protective clothing, disinfection and distilled water. Filling a reference bottle and carrying out the subsequent process takes an average of 143 minutes.

2.2 | Mother's own milk

According to our guidelines, mother's own milk is microbiologically tested on day seven. This costs €9.75 for laboratory materials and €26.40 for labour costs (Table 1).

If the mother has positive cytomegalovirus immunoglobulin G antibodies and negative cytomegalovirus immunoglobulin M antibodies, the milk is pasteurised until the infant reaches 32 weeks of postmenstrual age. The additional costs of pasteurisation are €3.51 per litre.

2.3 | Data collection and evaluation

The data were collected using a document and process analysis and a time measurement study. The document analysis was based on the hazard analysis and critical control points concept as well as the standard operating procedures and invoices provided by the hospital's medical purchasing team. The process analysis was conducted 6.00 AM to 2.30 PM, five days a week, for three weeks in April to June 2017. The observation took place in the sterile and non-sterile areas of the milk kitchen and in the milk bank. The activities were grouped into seven subprocesses (Figure 1): interviewing the donor,

using a breast pump to collect the donated milk, preparing the microbiological studies, separating the milk after receiving the results, pasteurisation and the final consultation with the donor so that they could return the breast pump they borrowed.

The data were collected according to established methods.^{19,20} The time measurement study was performed by external recording using a stopwatch method and standard data questionnaire. The time data were measured by an independent observer, with no links to the milk bank, and recorded on a survey sheet.²¹ The staff were fully aware of the presence of the observer, whose role was to carry out temporal measurements of all the direct and indirect activities of the milk bank employees. Before the time measurements were carried out, we identified 46 important activities and processes that needed to be included in the analysis, and these activities were observed a total of 357 times during the survey.

2.4 | Cost concepts (Figure 2)

When the cost per production unit was being determined, it was important to make the distinction between direct costs and overheads. Direct costs are directly attributable to a costing unit, such as the bottles, the pump sets and the agar plates. Overhead costs cannot be directly attributed to a costing unit, such as depreciation, personnel costs and electricity costs.²¹

Fixed costs are incurred as part of the total costs, even if no output is produced, by maintaining operational readiness. Variable or quantity costs are part of the total costs, and the amount depends on the output volume.²² Marginal costs are the additional costs for one additional unit.²²

We also included non-departmental services, which included the Institute of Hygiene and Environmental Medicine, the Central Laboratory and the Institute of Microbiology. In addition to the direct costs for a litre of milk, the Institute of Hygiene and Environmental Medicine charged €26.40 for a 60-minute report.

The total costs were calculated as the fixed costs plus the variable costs, which increased linearly with the amount of donated milk produced. The unit costs were the fixed costs divided by the amount of donated milk and the variable costs. A more detailed explanation of the calculations can be found in Appendix S1.

The data were entered into Excel 2016 (Microsoft Corp, Washington, USA) and analysed.

3 | RESULTS

3.1 | Production output

An average of eight donations was needed for a litre of donated milk. The average amount per donation was 140 mL, and the average amount received from each donor was 10 L. The donor milk mainly came from women who made donations while their own preterm babies were in the unit. In 2015, 15 donors supplied 50

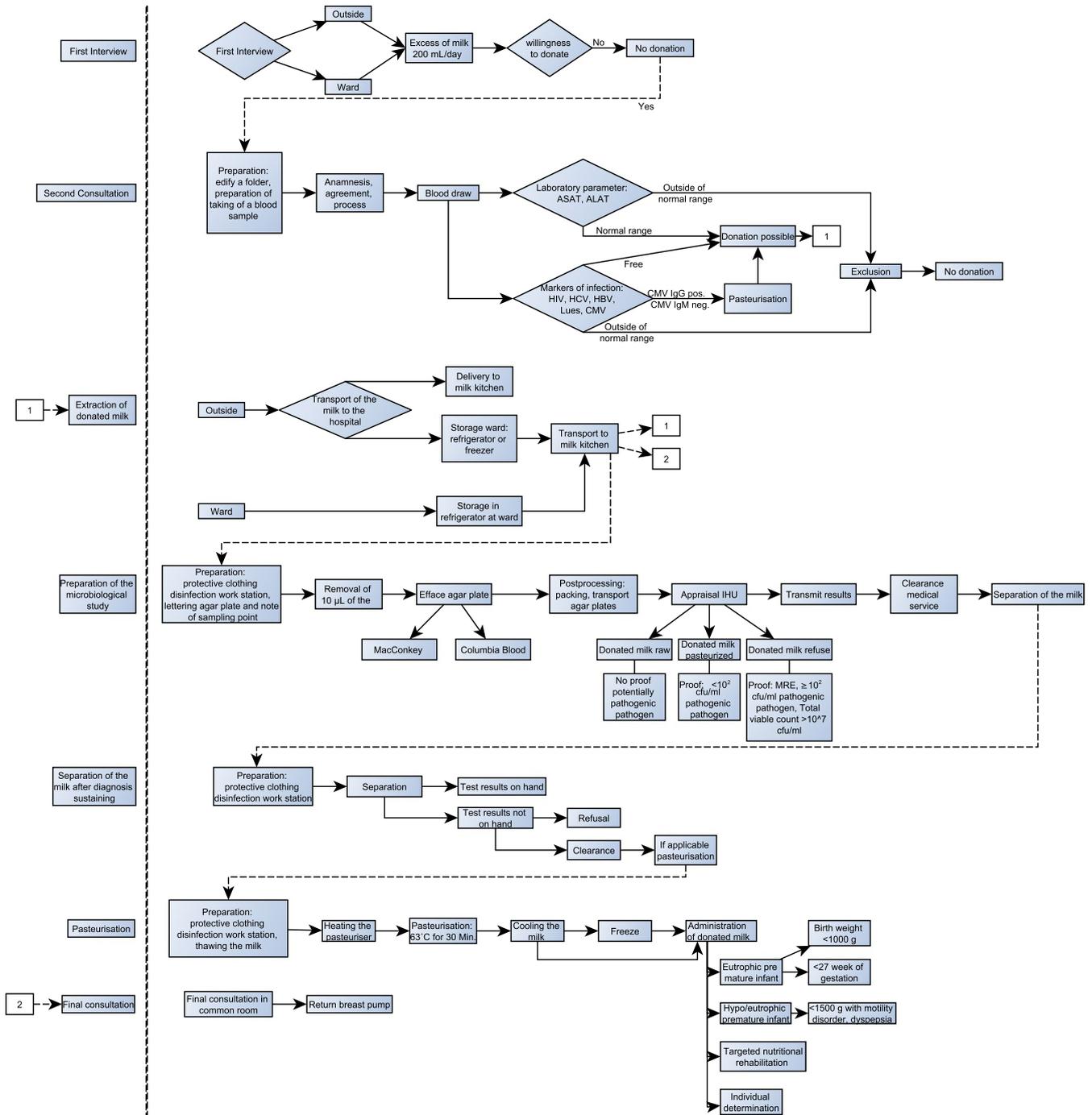


FIGURE 1 Sequence of operation diagram

premature babies. In 2016, 10 donors supplied 31 premature babies (Table 2). The main reason for donated samples failing clearance was an excessive microbial load. The raw milk was pasteurised at more than 10^2 microbial counts per sample to achieve a 95% reduction of microbial counts per sample. The amount of milk that was discarded was not affected by the number of women who provided donations at various stages during the study period. On average, preterm infants were given donated milk for 19 days at a mean intake of 173.05 mL/days. After that they received breast milk or, if that was unavailable, they had formula from a postmenstrual age of 32 weeks.

3.2 | Recording the subprocesses

A detailed description of the subprocesses and associated personnel costs are provided (Figure 1 and Table 3).

3.3 | Costs

The total cost for 300 L of milk supplied by donors during the study period was €92 085.02, and the average cost was €306.95 per litre. Figure 3 shows the total and unit costs depending on the amount of

donated milk. The marginal cost for one litre of donor human milk was €82.88 for each additional litre and €14.34 per day of care, based on 173.05 mL per day per infant. The marginal cost for formula was €10.28 for each additional litre and €1.78 per day of care, and the figures for unpasteurised mother's own milk were €38.42 and €6.65, respectively. The additional costs of using milk were €12.56 per day or care for formula and €7.69 per day of care for unpasteurised own mother's milk.

4 | DISCUSSION

Providing preterm infants with breast milk has been associated with a lower incidence of severe complications. If milk is not available from the infant's own mother, then donor human milk is an alternative that can provide these benefits for preterm infants. This was the first cost analysis for a German milk bank, and it showed that the marginal costs, as well as with the costs per care day of feeding a preterm infant donor human milk, was eight times higher than artificial formula.

The largest cost elements were personnel (51%), materials (27%) and overheads (22%). The most time-consuming activities were discussions with the donor (68 minutes), cleaning and disinfecting the workplace (30 minutes) and documentation (23 minutes).

Each subprocess in the milk bank had to be disinfected twice, including intermediate disinfection and cleaning for soiling. There was no potential for reducing this. Furthermore, the processes that involved the donors were highly time-consuming. However, contact between the milk bank and donor was important to gain trust.

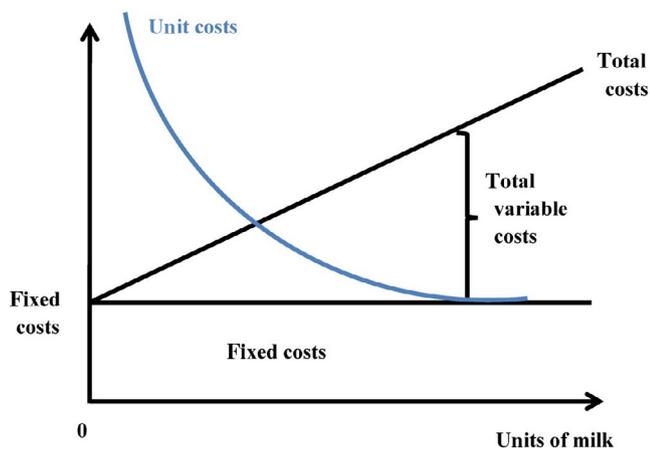


FIGURE 2 Total costs, unit costs, fixed costs and variable costs. Source: Illustration based on Wöhe and Döring²²

Finally, switching to electronic documentation could reduce the time spent in each subprocess.

The marginal cost of the donor milk was € 82.88. This included the cost of the second conversation with the donors (€26.95), which was high because it included taking blood and providing them with the bottles for their donor milk. The other relatively high cost was the microbiological examination (€22.90), particularly the high material and diagnostic costs. Feeding unpasteurised donor human milk requires frequent bacterial testing. Therefore, it would be possible to cut costs by feeding the infants pasteurised donor human milk, in accordance with the international recommendations.^{9,23} We have fed unpasteurised donor human milk in Greifswald since 2014,¹⁵ which is a rare practice in Europe. In our unit, we found that the rate of NEC in VLBW infants decreased from 8.23% in 2010-2014 to 3.62% in 2015-2018, and the standardised rate of nosocomial infections, which was the number of observed infections divided by the number of expected infections, decreased from 1.32 to 0.76. A value of less than one was better than expected, and a value of more than one was worse than expected. Before 2014, donor human milk was completely pasteurised and was not available for all VLBW infants who could be fed with their own mother's milk.

The times shown in Table 3 refer to the one-time performance of an activity. While activities, such as documentation and microbiological testing repeatedly occurred for each litre of donor human milk, the discussion on the course of breastfeeding during the second interview only occurred once. Thus, the time required for handling a litre of donor human milk averaged 493 minutes. However, we did not just process one litre of donor human milk at a time, and this resulted in much lower marginal cost of €82.88.

It is useful to compare this first cost analysis for donor human milk in Germany with other studies. Studies from the United States have calculated that one litre of donor human milk cost approximately US \$150.^{24,25} Our analysis yielded a marginal cost per litre of donor human milk of €82.88. The costs shown arise from the perspective of the milk bank as the manufacturer of donor human milk. The cost to the hospital for donor human milk is higher because, for example, unused milk must be discarded. In this analysis, we did not take into account the costs for the rooms required for the process or for the purchase of equipment. This was for two reasons. The first was that they were not relevant to the relatively short period covered by the study, and the second was that Government funding and health insurance funds new equipment and running costs, respectively.

Current cost-benefit analyses suggest that the significantly higher daily costs for donor human milk can be justified from a health economic point of view. A study from Chicago showed that after controlling for NEC in a regression analysis, each additional mL/kg/

TABLE 2 Production output donated milk in litre

Year	Donated milk	Clearance total	Clearance raw	Clearance pasteurised
2015	186.1	163.1	102.4	57.7
2016	69.8	40.5	15.4	25.2

Subprocesses	Personnel expenses in Minutes:Seconds	Standard deviation in Minutes:Seconds
First interview		
Ward	06:37	00:50
Telephone call	04:35	0
Second consultation with the donor		
Preparation	23:27	1:02
Conversation	52:07	2:27
Extraction of donated milk		
Transport from ward to milk bank	03:37	00:07
Acceptance of the milk	02:29	00:51
Preparation of the microbiological study		
Preparation	05:30	01:36
Converting of the Agars	22:46	00:39
Postprocessing	40:43	02:10
Separation of the milk		
Preparation	04:54	01:36
Separation	00:52	01:17
Postprocessing	03:48	01:35
Pasteurisation		
Preparation	37:19	01:36
Heating the pasteuriser	45:00	0
Pasteurisation	30:00	0
Postprocessing	30:29	01:35
Final consultation		
Conversation	10:30	0
Return breast pump	19:50	0
Non-departmental service: IHEM appraisal	60:00	0
Ward		
Medical service: Clearance of the milk	02:30	0

Note: IHEM Institute of Hygiene and Environmental Medicine.

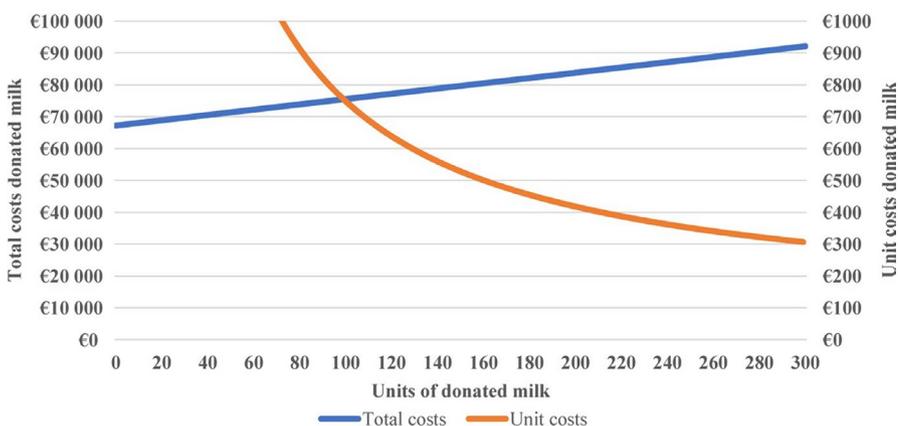


TABLE 3 Personnel expenses and standard deviation of the production of a litre donated milk

FIGURE 3 Total costs and unit costs per litre donated milk
SOURCE : Authors' illustration

day of human milk during the first 14 days of life was associated with a significant reduction of NICU costs by US \$534.²⁶ In contrast, a Dutch multicentre study showed no benefit from pasteurised donor human milk formula in terms of the incidence of NEC, infections and mortality.²⁷ However, donor human milk was only fed for 10 days in that study, while the German Neonatal Network study, detailed in the Introduction, analysed the exclusive diet with maternal breast milk.⁴ A systematic analysis by Buckle et al from seven studies on the costs of donor human milk and 17 studies on the costs of NEC also showed a positive cost-benefit ratio.²⁸ Kantorowska et al also demonstrated that setting up milk banks and increasing the use of donor human milk in several US clinics had reduced the NEC rate.²⁹

In order to be able to determine the macroeconomic advantages of donor human milk by reducing the incidence of NEC, an analysis of the life-time costs would be particularly important. However, this would also be very expensive. Significant savings would also be made after the newborn infant aged, as children who do not have NEC are generally healthier as they grow older. The analysis presented here provides the basis for another interesting research approach. In Germany, hospital reimbursement rates are determined by the German Diagnosis-Related Group System. For example, if a hospital treats an infant with a birth weight ranging from 495 to 1300 g without NEC, and without prolonged ventilator support, it will receive €26 341 to €129 938, depending on the patient's birth weight. Each case of NEC requiring surgery and prolonged mechanical ventilation results in additional reimbursement of €21 242 to €47 404. Therefore, considerable savings can be made during the first hospital stay if a preterm infant does not have NEC.

As mother's own milk is preferable to donor milk, promoting breastfeeding should be the priority in neonatal units, in order to reduce the complications of preterm birth.⁸ This approach also has its costs. Preterm and sick infants have different needs to healthy infants and require different treatment settings. It is important to have specific breastfeeding policies for neonatal intensive care units and ensure that the healthcare professionals who look after these patients have the knowledge and skills they need to advise on lactation and provide breastfeeding support.³⁰ However, there are also costs associated with getting a Baby-Friendly Hospital Initiative certificate.

4.1 | Strengths and limitations

The strength of the study was that the study hospital had decades of experience of using donor human milk, and its milk bank was completely technologically upgraded and reorganised in 2014. All workflows, limits and indications have been redefined and standardised in collaboration with the Institute for Hygiene. This means that the data in this study, and the underlying structures, are very up to date. The detailed cost analysis was carried out during a very detailed three-week observation of all work processes. A limitation is that we did not analyse the investment costs. However, major construction work is very site-specific and creates very variable costs.

5 | CONCLUSION

Feeding preterm infants with donor human milk was associated with significantly higher costs. Donor human milk is more expensive than mother's own milk, and processing mother's own milk is more expensive than using formula. With respect to the preventive benefits associated with donor human milk, these data may serve as a basis for financing donor human milk within healthcare systems.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Fengler J, Heckmann M, Lange A, Kramer A, Flessa S. Cost analysis showed that feeding preterm infants with donor human milk was significantly more expensive than mother's milk or formula. *Acta Paediatr.* 2020;109:959-966. <https://doi.org/10.1111/apa.15087>