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Hearts Milk Bank: developing the 'bank with a difference'

The recently established Hearts Milk Bank has recruited over 150 human milk donors in the first 10 months of operation and currently supplies screened and processed donor human milk to 20 NHS neonatal and paediatric units that had previously struggled to obtain an assured supply. A programme of research and innovation is being initiated with the aim of understanding the optimal processing and use of donor human milk, as well as answering fundamental questions about the constituents and function of human milk.

Gillian Weaver
BSc Hons (Nutrition), RD
Director and Co-Founder

Natalie S. Shenker
BM BCh, MRCS, MSc, PhD
Director and Co-Founder
natalie@heartsmilkbank.org

Hearts Milk Bank, Hertfordshire

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Key points

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1. The Hearts Milk Bank was established in June 2017 to address the lack of equity of access to donor human milk.
2. It supplies donor human milk to neonatal and paediatric units throughout the south and east of England as well as to a small number of infants being cared for at home.
3. A variety of Hearts Milk Bank initiatives aim to increase awareness of the science underlying lactation, breastfeeding and human milk.

Background

In 2015 the British Association of Perinatal Medicine (BAPM) convened a working party to develop a framework for practice for the use of donor human milk (DHM) in the UK. Published in July 2016, the framework[1] provides a summary of milk banking activity in the UK, as well as recommendations for the future provision and use of DHM. The primary key conclusion of the BAPM working group was: "Current usage of pasteurised DHM varies across the UK and is not universal."

Data from UK milk banks collated by the UK Association for Milk Banking (UKAMB) between 2012 and 2014 highlighted the variability between UK milk banks, with donor recruitment ranging from 26 to 248 donors per year and two-thirds of human milk banks recruiting fewer than 100 donors per year (unpublished data, UKAMB audit). The provision of pasteurised DHM ranged from 21 to 1,750 litres, with more than 50% of milk banks issuing fewer than 500 litres of DHM. The frequency of provision to individual neonatal units also varied widely from very occasionally (once or twice a year) to weekly.

The BAPM working party's report noted that there was no nationally coordinated service across the UK, which meant that universal access to DHM did not exist. However, this applies mainly to units in England and Wales. One Milk Bank for Scotland based at the Queen Elizabeth University Hospital Maternity Unit in Glasgow provides a pan-Scotland service. Similarly, the Human Milk Bank located in the South West Acute Hospital in Enniskillen, Northern Ireland, supplies DHM throughout the whole of Northern Ireland as well as to hospitals in the Republic of Ireland. In England, Southwest Neonatal Network Donor Milk Bank at Southmead Hospital in Bristol has, in recent years, been funded as part of a pilot study to supply milk throughout the southwest of England, while the Northwest Human Milk Bank based in the NoWFOOD Centre at the University of Chester covers hospitals across much of the north of England as well as hospitals throughout Wales.

The rest of England has a much less consistent and assured supply, with NHS Trust-based milk banks largely funded and resourced to only supply their own neonatal unit/s. However, despite having the greatest number of milk banks the southeast of England, including London, was where neonatal units seemed to have the most difficulty accessing an assured supply, unless they had an in-house milk bank. In 2016 and 2017, even that was no guarantee that DHM would always be available.

The BAPM framework also concluded that evidence from randomised controlled trials, observational studies and systematic reviews had not raised major concerns regarding the safety of DHM. Finally, it highlighted the urgent need for improved evidence of the efficacy and cost-effectiveness of DHM to determine the optimal indications for its use and provision. Since the publication of the BAPM framework, additional findings have been published that support the use of DHM rather than preterm formula as a

supplement to maternal milk. These include a reduction in the incidence of necrotising enterocolitis, retinopathy of prematurity and bronchopulmonary dysplasia.[2-5] However, each study has methodological issues, largely as a result of too few infants to make firm conclusions. The authors fully support additional trials where the current evidence base is inconclusive or not yet available and acknowledge the need for further evidence underpinning the wider use of DHM.

The growing demand for DHM

Given the widely differing use of DHM both geographically and clinically, the authors were convinced that an assured supply of DHM throughout the whole of the UK was needed to meet the current clinical demand as well as to support an improved evidence base. This growing demand has been driven by recommendations from both the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)[6] and the American Academy of Pediatrics.[7] Both recommend, in common with the World Health Organization and Unicef,[8] that DHM should be the chosen alternative when maternal breast milk is not available. Each body also states that DHM should be provided from an established human milk bank that follows specific safety guidelines. In the UK these are available in the form of the National Institute for Health and Care Excellence (NICE) clinical guideline 93 (CG93, 2010) entitled *Donor Milk Banks; Service Operation*.[9]

Hearts Milk Bank

Hearts Milk Bank was founded as a Community Interest Company (a not-for-profit social enterprise) in 2016 by Dr Natalie Shenker, a former trainee paediatric surgeon with a PhD in epigenetics, and human milk banking specialist Gillian Weaver. It became fully operational in June 2017 and was established primarily to address the lack of equitable access to donor milk for preterm and low birth weight infants throughout the southeast. A secondary objective was to facilitate the wider use of DHM and so enable clinicians to offer an exclusive human milk-based diet to moderate or late preterm infants, as current rationing means that DHM is largely prioritised to babies born at a very low birth weight. Additionally, DHM could also be made available to term infants with additional health needs, including congenital cardiac anomalies, a requirement for gut and other surgery, and feeding intolerances. In the UK these infrequent uses for DHM are only usually possible in units with an attached milk bank, despite experiences from overseas reflecting that these conditions are routine indications for DHM use (**TABLE 1**). Improved access to DHM without issues of availability would provide opportunities for clinicians and, importantly, clinical researchers to explore the wider potential benefits of an exclusive human milk diet.

Documented or known use of DHM beyond the extremely preterm population

- Infants with cardiac anomalies
- Infants where mother is in intensive care or there is maternal cancer
- Child liver or bone marrow transplant
- Term babies with renal problems
- Term babies of diabetic mothers
- Infants with gastroschisis, diaphragmatic hernia, Hirschsprung's disease or ulcerative colitis

Known uses of DHM globally

- Babies born to mothers who are HIVpositive
- Diarrhoeal diseases
- Formula or cows' milk intolerance
- Cancer in the baby
- Infants who have been adopted or born through surrogacy where the mother is unable to provide milk

TABLE 1 Uses of donor human milk (DHM).

The authors also anticipated the demand for provision of a limited supply (eg 1-3 months) of DHM for those infants with no access to an alternative supply. Such cases include infants born to mothers who have previously undergone a double mastectomy, mothers undergoing chemotherapy and mothers with a need for medications that contraindicate breastfeeding. The use of DHM in the support of HIV positive mothers is also supported by the Hearts Milk Bank. Given the acknowledged short, medium and long-term health benefits of a human milk diet[10] and the high levels of retention of many of the bioactive components following pasteurisation,[11,12] as well as minimal nutritional losses, DHM may be of benefit to a wide range of infants without access to maternal milk.[8]

Establishing the Hearts Milk Bank

One of the first tasks upon embarking on the development of Hearts Milk Bank was to ensure appropriate clinical governance. A team of nationally and internationally acclaimed experts from all relevant fields was assembled.[13] Together they provide the necessary breadth of clinical, microbiological, pharmaceutical, business and logistics expertise. Chairman of the Hearts Milk Bank board Graeme Allinson, with his background in banking and support for small to medium sized enterprises, concentrates minds on the need for developing and maintaining a financially sound foundation to create a sustainable organisation. Lactation support is readily available thanks to the recruitment of several members of staff with wide-ranging breastfeeding support experience, including an International Board Certified Lactation Consultant (IBCLC). Support from the University of Hertfordshire (UH) has been ongoing and this is reciprocated by a wide range of collaborations and student placements at Hearts Milk Bank. These include midwifery and nursing student placements in the milk bank, visiting lectureships and future planned research projects. One publication has already resulted from an elective placement by second year UH midwifery students.[14]

The practical obstacles to establishing the UK's first fully independent human milk bank were largely two-fold:

1. sourcing suitable and sufficient funding to enable the enterprise to proceed
2. finding appropriate premises.

The first breakthrough came with the offer of a year's mentorship and ongoing support from Cambridge University's Judge Business School via its Cambridge Social Ventures programme. This initiative is an accelerator that supports selected businesses with identified positive social and environmental impacts. This was followed by enrolment on the UK division of the global start-up business 'incubator' programme, Mass Challenge UK. In September 2016 Hearts Milk Bank won a highly prestigious place as one of the 100 finalists from 1,400 applicants. Four months later the authors were one of six winners awarded a £10,000 prize. A crowdfunding campaign and additional donations enabled a rapid start to equipping the laboratory and office space located in the UH Biopark facility in Welwyn Garden City, just north of London. The location was chosen with transport links in mind, given its closeness to a series of motorways and ease of access into London.

From the outset, the founders were determined to provide access to an assured as well as safe supply of DHM for those hospitals without such a service or that had faced past difficulties in sourcing local supplies of DHM. Having worked for over 25 years to support most of the UK's human milk banks via the UKAMB – either while they were being established or to help maintain and improve their services – the founders were determined not to compete with or undermine any of the existing milk banks. Rather, the Hearts Milk Bank was developed as a means of bridging the gap in provision that had been clearly identified by UKAMB, BAPM and NICE.

Having recruited over 150 donors in the first 10 months of operation, Hearts Milk Bank is currently supplying screened and processed donor human milk to 20 NHS neonatal and paediatric units throughout the south and east of England as well as to a small number of infants being cared for at home. All of the recipient hospitals had struggled in the past to obtain supplies of donor milk or had not initiated use because of the lack of an assured supply.

Since opening, the Hearts Milk Bank has referred over 50 prospective donor mothers to their local milk bank and has actively collaborated with a number of hospital-based banks in the south and east of England as well as further afield. A planned series of bi-annual seminars on topics related to infant feeding and the use of DHM will be aimed at nursing, medical and dietetic staff working in hospitals that use DHM from Hearts Milk Bank and others wishing to attend. These will form an additional part of the education and training programme that is currently provided to hospital neonatal units by Hearts Milk Bank staff. The goal is to ensure that hospital staff have confidence when discussing DHM use with parents and carers and are able to take fully informed consent for its use. Leaflets and consent forms have been specially designed to facilitate this and future versions of the website will enable appropriate information to be readily accessible.

Transportation of DHM

A crucial part of the proposed provision of DHM throughout the southeast depends upon its rapid and safe transportation as and when requested, and also an efficient collection service for milk from donors.

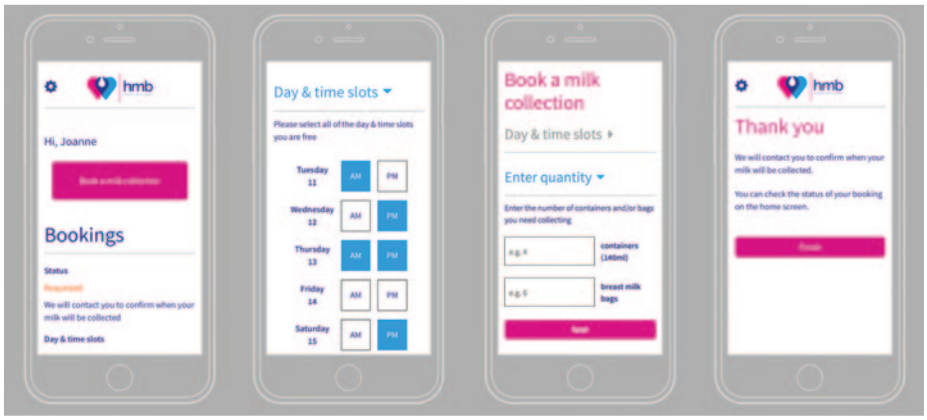

FIGURE 1 The Hearts Milk Bank app, funded by a grant from the National Endowment of Science, Technology and the Arts. The app was launched in January 2018 and is currently in use by 35 donors.

FIGURE 2 Above: The Hearts Milk Bank team preparing containers for use in the biosafety cabinet (background) to process donor milk. Right: A bar-coded bottle of DHM.

Volunteer motorcyclists and drivers, often known as 'blood bikes', have been engaged in supporting many of the milk banks throughout the UK for several years. The local Hertfordshire and Bedfordshire SERV (Service by Emergency Rider Volunteers) group has worked with Hearts Milk Bank from the outset. SERV and similar groups operate an almost nationwide service by coordinating collections and deliveries to ensure the frozen milk, appropriately transported in accordance with NICE guidance,[9] arrives safely at its destination after a minimum journey time.

Hearts Milk Bank is now supported by blood bike groups throughout the south and east of England, which coordinate relays to deliver and collect milk over a wide geographical area. The frozen milk is mainly couriered by motorcyclists but cars are also available for larger volumes of milk and during adverse weather conditions. In addition, a crowd-funding campaign enabled Hearts Milk Bank to adapt a small economical 'milk mobile' – a car that is used when needed for an emergency delivery or collection of donor milk.

Milk donation

The process of milk donation has changed little over recent decades and donors can frequently feel frustration in communications with milk banks. The Hearts Milk Bank was awarded a grant by the National Endowment of Science, Technology and the Arts (Nesta) to develop the first of a series of web-based apps, which enable the donor to organise milk collections simply. The resulting app facilitates the coordination of collections of milk from donors' homes by providing the donors with direct contact with the SERV coordinators and riders, while the Hearts

Milk Bank team can monitor the timing and volume of collections (**FIGURE 1**). Future projects will enable donors to follow the progress of their milk through the milk banking process (with automatic updates when their milk has been issued to a hospital neonatal unit), and allow the milk bank to work with the donor to reduce bacterial contamination of expressed milk. Full anonymity is maintained for donors but the information gives added reassurance to the donors that their milk is valued and being used in support of babies as intended. Once fully validated and approved, the app will be made available to enable other UK milk banks to benefit from its development.

Full compliance with the NICE guideline demands complete traceability of all the milk donated to the bank – from donor to the final recipient. A milk bank undertakes to maintain the relevant records for 30 years. In common with all other products of human origin, full traceability is greatly facilitated by the use of barcode tracking systems. In the case of human milk banks, several tracking systems that have been developed in recent years are commercially available. The Hearts Milk Bank has been instrumental in the development and fine tuning of a bespoke tracking system aimed at both UK and overseas milk banks. Further advantages of this system, which uses ISBT128, the international system for standardised coding and labelling, are the built-in auditing and reporting facilities (saving staff time) and the ease with which recipient hospitals will also be able to monitor and record donor milk usage (**FIGURE 2**).

Research and innovation at Hearts Milk Bank

A programme of research and innovation is now being initiated, with the aim of understanding the optimal processing and use of DHM, as well as attempting to answer fundamental questions about the constituents and function of human milk.

Throughout the phases of planning, developing and establishing the Hearts Milk Bank, the authors have maintained support for maternal lactation and breastfeeding as the primary goal for all of the milk bank's activities. Increasing awareness of the science underlying human milk has been the driving force behind all of the initiatives of the bank and underpins its initial engagement with new users of DHM. This drive has also produced new

FIGURE 3 An infograph of human milk components produced as a collaboration between Hearts Milk Bank and Tiny Humans.

materials in collaboration with other organisations, including Tiny Humans (www.human-milk.com; **FIGURE 3**) and the GP Infant Feeding Network (www.gpifn.org.uk).

Hearts Milk Bank will be the recruitment hub for the Breast milk Epigenetics Cohort Study – a prospectively collected bio-resource of milk and blood samples along with demographic data from 20,000 women. This partnership with Imperial College London aims to understand the links between human milk components and the protection of maternal health, including the reduced risk of triple negative breast cancer, ovarian cancer, type 2 diabetes and cardiovascular disease.

A recent collaboration with the Wellcome Trust-funded Parenting Science Gang resulted in over 100 mothers of babies from three months to four years gathering at Charing Cross Hospital in London to express samples of their milk.[15] This research project is targeting nutritional and immunological components using cutting-edge science and technology in development at Imperial College, London, and will be followed by a range of research studies that aim to further our understanding of human milk.

Conclusion and acknowledgement

The authors' vision throughout has been to help make DHM the first line supplementation for infants in hospital whenever maternal milk is insufficient, in the context of optimal help and support for the mother and baby to breastfeed. We are grateful to everyone who has supported the development of the UK's latest milk bank; in particular, the active support from the Unicef Baby Friendly Initiative team in aiding the recognition of the need for equitable access to DHM throughout the UK and the importance of developing a service that meets the needs of families and healthcare professionals.

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