British Association of Perinatal Medicine

The Use of Donor Human Expressed Breast Milk in Newborn Infants

A Framework for Practice

July 2016

Executive summary

Key conclusions

1. Current usage of pasteurised donor human milk (DHM) varies across the UK. This reflects local availability as well as differing opinions amongst health professionals of its benefits. Parents general welcome the option of DHM when mother's own breast milk is not available.
2. DHM is considered by some, but not all practitioners, as being integral to the promotion of breast feeding. The availability of DHM may have wider impacts, for example, on maternal breast feeding rates and both positive and negative impacts have been reported. However a recent meta-analysis concluded that the overall impact is positive.
3. Milk banks vary in size and output. There is no nationally coordinated service which means that universal access to DHM does not currently exist.
4. The existing evidence from controlled trials, observational studies and systematic reviews has not raised major concerns regarding safety.
5. There is currently inadequate evidence to make firm recommendations for use. Improved evidence of efficacy and cost-effectiveness is urgently needed to determine the optimal indications for use and provision of DHM

Main recommendations

1. Further work to examine the efficacy, cost-effectiveness and indications for use and provision of DHM is urgently required. Outcomes should include both short and longer term effects for baby and mother as well as wider societal effects and health economic evaluation.
2. If DHM is shown to be of benefit, universal access across the UK will require a safe and sustainable infrastructure for supply, processing and delivery. Funding will need to be identified, and the process supported by robust auditing of practice.
3. In the absence of high quality data, individual networks and hospitals should continue to develop their own policies and procedures for the use of DHM. NNUs should be encouraged to participate in high quality research to bring about rapid resolution of these important, continuing uncertainties.

Contents

Background, General Terms and Purpose

The aim of the working group was to produce a framework of best practice for the use of donor human expressed breast milk (DHM) for newborn infants in the UK. This was considered important in the context of:

(1) Increased awareness of, and demand for, DHM in the care of preterm infants, particularly as potentially preventable serious morbidities such as necrotising enterocolitis (NEC) and infection remain major challenges;

(2) National and international recommendations for milk banking and the use of DHM (reference to NICE, PATH, AAP, ESPGAN and WHO);

(3) Increased research in the area of feeding and nutrition, and the formation of the UK Neonatal Nutrition Network;

(4) Lack of high quality evidence of the efficacy of DHM in the UK population of preterm infants

(5) NICE guidance on DHM: **http://guidance.nice.org.uk/CG93** covering only:

a. How milk banks should recruit, screen and support women who donate breast milk
b. How milk banks should handle and process the breast milk they receive from donors
c. The tracking and tracing of donors and recipients of DHM

Specifically NICE guidance does not consider:

a. The indications for use of DHM including definitions of at risk groups that might benefit
b. What the benefits of feeding DHM are
c. The care and treatment of babies who receive DHM
d. How mothers should handle and store breast milk for their own babies

The remit of the BAPM working group was to focus on the practicalities of the use of DHM in UK neonatal units (NNU). The term ‘use’ includes current users and those who could be users. The group aimed to describe issues around access to DHM for those who want to use it. NICE guidelines already exist for operational aspects of human milk banks (HMB) therefore the group only considered milk banking in relation to HMB geographical location

(across the UK, and co-location with NNU) and whether this impacts on the supply or use of DHM. The group did not consider the issue of 'breast milk sharing' (the informal practice of mothers giving milk to friends or buying breast-milk). The group recognised however, that this is an important issue in many parts of the world, that the extent of such practice in the UK remains to be determined, and that the practice is likely to have socio-cultural dimensions.

Specific tasks undertaken by the group as defined by the BAPM ToR included:

1. Reviewing the literature on the benefits and risks of using DHM in different populations of newborn infants;
2. Referencing data on relevant morbidities in UK (e.g. NEC) that might be used to inform a best practice document;
3. Develop a framework for practice for the use of DHM.

Group membership

- Chaired by Dr Nick Embleton, Consultant Neonatal Paediatrician, Newcastle – appointed by BAPM's Executive Committee
- Other group members (self-nominated from BAPM membership and approved by Executive Committee)
- Ms Debbie Barnett, Donor Milk Bank Co-ordinator, Glasgow
- Mrs Charlotte Oates, Donor Milk Bank Manager, Southampton
- Ms Jennifer Griffiths, Bliss
- Dr Judith Simpson, Consultant Neonatologist, Glasgow
- Mrs Helen Smith, Infant Feeding Lead Nurse, Newcastle
- Ms Kate Tavener, Neonatal Dietitian, London
- Dr Merran Thomson, Consultant Neonatologist, London
- Ms Gillian Weaver, Dietitian and Milk Bank Manager, London
- Dr Thomas Williams, ST3 Paediatrics, Edinburgh
- Ms Lisa Nandi, Executive Manager, BAPM
- Mrs Lynne Radbone, Dietitian, Cambridge

The group met on two occasions at the RCPCH, London (June and November 2014) and conducted electronic correspondence between these meetings. Minutes of these meetings along with declaration of any conflict of interest are available from BAPM (LN). Given the complexity of the topic, and the backgrounds of group members, it is important to note that consensus guidelines on usage could not be agreed. This further strengthened the group's desire to produce a framework, and to support strongly further research in this area.

Background and context for the use of DHM

Over the last two decades mortality rates for very low birth weight (VLBW) infants have fallen substantially, although this has not been mirrored by a similar decline in neonatal morbidity. This morbidity plateau has been attributed, at least in part, to the combined challenges of infection and necrotising enterocolitis (NEC) (Fanaroff et al, 2007, Stoll et al, 2010).

Infection is an increasingly prevalent cause of death in preterm infants (Berrington et al, 2012), and like NEC is an independent risk factor for adverse long term developmental outcomes (Alshaikh et al, 2013). Late onset sepsis (>72 hours postnatal age) is inversely related to gestational age, with an incidence of up to 15% in VLBW infants (Vergnano et al, 2011). Quality improvement interventions including antimicrobial stewardship, central line care bundles and the early introduction of enteral feeds are important, cost-effective strategies in sepsis prevention (Shane and Stoll, 20142014).

NEC is a multifactorial disease and may be difficult to diagnose accurately in clinical settings. The incidence is closely associated with gestational age, and it occurs in 5-10% of very preterm infants, but is increasingly rare in infants >28 weeks gestation. The UK Neonatal Collaborative NEC study (Battersby et al. personal communication) has produced accurate UK wide data on gestation specific incidence. Approximately 30-50% of affected cases require surgery and may die (Henry and Moss, 2008). In addition survivors are at risk of a range of short and long term sequelae including; prolonged dependence on parental nutrition, central line associated sepsis, cholestasis, poor growth, short bowel syndrome and impaired neurodevelopment (Rees et al, 2007, Pike et al, 2014). The economic impact of NEC-related morbidity is significant; the estimated cost of treating an infant with short bowel syndrome secondary to NEC is difficult to determine but US studies estimate costs may be as high as $1.5 million (US dollars) over five years (Ganapathy et al, 2013). Strategies to protect the preterm gut and prevent NEC are therefore essential aspects of quality improvement programmes (so called “NEC care bundles”), as well as important research priorities. Future studies may be informed by the findings of the UK Neonatal Collaborative NEC study which is currently collating data from the majority of UK neonatal units, and aims to identify enteral feed related antecedents to NEC.

Whilst it has never been subject to randomised controlled comparisons with formula milk there is strong indirect evidence that maternal breast milk (own mother's milk, OMM) confers many health advantages to preterm infants. These effects appear to be dose dependent and include a reduced incidence of NEC and late onset sepsis, likely due to a combination of immune modulation and gut priming with beneficial bacteria (Menon and Williams, 2013). Unfortunately even with intensive breast feeding support maternal milk may not be available in sufficient quantities (Smith et al. 2014) and in this situation DHM may be used as an alternative or complementary feed. There are occasions when OMM is not available or specifically contraindicated; examples include HIV positive mothers, maternal chemotherapy and other drug treatments, mothers who have undergone double mastectomies and infants born through surrogacy. Individually, whilst these indications are uncommon (<5% of all admissions), they represent an important group for units to consider (Smith et al. 2014).

DHM is fundamentally different from fresh OMM. It is commonly donated by mothers of term babies when their babies are several weeks old and in the UK, all DHM is heat treated, frozen and stored prior to administration. Thus the quality and therefore the potential benefits of DHM, are probably different from OMM (Lawrence RA 2001). Increasingly mothers of preterm infants donate surplus breastmilk stored whilst their babies were receiving neonatal care. The recently updated Cochrane review of formula milk versus DHM for feeding preterm infants confirmed that formula feeding is associated with an increased incidence of NEC, with a risk ratio of 2.77 (95% CI 1.40 to 5.46) (Quigley and McGuire, 2014) but there are a number of important methodological limitations in determining efficacy for preterm infants which include:

1. The historical nature of the majority of the included trials. Of the 9 studies included in the Cochrane review, 7 were published more than 30 years ago and were conducted in an era where neonatal populations and practices were vastly different
2. Most of the trials compared unfortified DHM to preterm formula, whereas in most UK situations currently DHM is used as a supplement to own mothers' milk (OMM), and is commonly has nutrient fortifiers added.
3. One trial (Schanler 2005) compared the use of DHM as a supplement to OMM, and one trial as sole diet (Cristofalo 2013). Neither of these studies showed a statistically significant reduction in NEC or invasive infection. In total these 2 recent trials represent only 220 infants enrolled in RCTs of DHM in the last 30 years.

It is clear that further well designed studies are required to clarify the role of DHM in typical UK settings where early enteral feeding, breast milk fortification and other nutritional strategies are increasingly common. The largest trial to date (The Early Nutrition Study Netherlands Trials Register - NTR3225) of DHM has yet to be published in a peer reviewed journal or abstract. Results of this randomised controlled trial were recently communicated in an invited presentation (Van Goudoever et al. 2015 Joint European Neonatal Societies, Budapest); in ~380 preterm infants (birth weight <1500g) randomized to either DHM or preterm formula to make up any shortfall in supply of OMM during the first 10 days of life there was no difference in either individual or composite primary outcomes of NEC, sepsis or death. The majority of milk received in each group was OMM, and survival was significantly improved in babies who received greater than 50% OMM in the first 10 days of life. Further research is needed to establish the role of DHM and preterm formula in a population of preterm babies where OMM is less available.

Current practice of HMB operation

This framework will not describe 'best practice' in human milk banking, but rather describe the history and development of HMB and current UK practice. DHM is donated by a breast feeding mother to a HMB to be fed to another mother's child. In common with milk banking traditions globally, the provision of DHM is without financial or other incentives and this is an important safeguard for mothers and babies alike. *(Ref: The Gift Relationship: From Human Blood to Social Policy LSE Books1997 Richard M Titmuss (Author), Professor Ann Oakley (Editor)).* However some countries within Northern Europe do reimburse mothers' expenses and in the United States, commercial organisations buy breastmilk directly from mothers as well as providing incentives to NNUs to obtain breastmilk.

HMBs have been in operation since the early 20th Century and were operational in most European countries by the late 1950's. Concerns about the potential for transmission of HIV via breastmilk led to mass closures in the 1980's however the availability of effective pasteurization equipment and routine serological screening of donors reversed this trend. Since the early 1990's many milk banks have opened. Worldwide, a total of over 500 HMBs are known to operate with more than 200 of these in Europe. In the UK, following recent mergers of two milk banks in the North West of England and two in the South East, fifteen HMBs currently operate (See Map in appendices). Scotland and Northern Ireland each have

a single bank that is funded, resourced and organized to provide DBM to all hospitals requesting it. (see appendix for case history). In England, milk banks are located mainly in the South and South East. The most productive bank in terms of donors recruited and litres of DHM supplied is the North West Human Milk Bank in Chester. Large areas of England and the whole of Wales do not have a local HMB however DBM is readily available on request to all English and Welsh neonatal units via the English milk banks listed (see appendix). Requests for, and the use of DHM, have been increasing year on year. Throughout 2014, four milk banks based in London routinely provided DHM to their attached neonatal units and to all the NNUs within the London Neonatal Operational Delivery Networks, although this is organized on an ad hoc basis.

Milk banks in England are mainly funded by individual NHS Trusts to enable guaranteed provision of DHM to that Trust's neonatal unit/s. Where there is surplus of pasteurised DHM, some HMBs make this available to neonatal units in other NHS Trusts. A charge is usually made for this service to cover the costs incurred. The costs vary according to staffing levels, staff bandings, activity levels and other costs (microbiological screen etc). All milk banks require pasteurization and other equipment that may only be used once or twice a week in the smaller operations. Donor recruitment, volumes of breastmilk collected and the amount of pasteurised DHM available vary widely between banks. Recommendations from a DH funded working group in 2004 that included an economic evaluation of the services operating nationally, suggested consideration be given to placing human milk banks within the remit of national blood services although this was not carried forward. This may have been due to resource issues that may have changed in the last 10 years.

Where DHM is provided to other NHS Trusts, the charge varies from £100 - £200 per litre which represents a cost of only £5 - £20 per day for the majority of infants receiving DHM. No profits are made in common with the UK provision of all products of human origin. The North West Human Milk Bank based in the University of Chester is unique amongst UK milk banks, in that it is largely self-funding via the provision of DHM to external Trusts. A fee of £125 per litre is levied. This milk bank processes the highest volume of DHM in the UK and so demonstrates the benefits of economies of scale.

Up until 2012 the costs incurred in transporting breastmilk from donor mothers to the milk bank and from milk banks to other hospitals limited the geographical areas covered. The

development of substantial links between milk banks and the SERV (Service by Emergency Rider Volunteers) and other similar groups has made the transportation of milk across greater distances feasible, increasing availability and use. These charitably funded groups exist throughout the whole of the UK and exist mainly to deliver blood and other essential or emergency supplies to hospitals out of normal delivery hours. Most of the UK milk banks now have contracts with these 'blood bike' groups. The volunteer riders undertake extensive training and are locally coordinated. The collection and delivery of milk is made free of charge to both milk banks and hospitals using these services, and this has underpinned the recent more widespread use of DHM.

Guidelines for the establishment and operation of milk banks in the UK were published by the British Paediatric Association in 1994 with revised editions later published by the UK Association for Milk Banking which were endorsed by the Royal College of Paediatrics and Child Health (1997, 2003). In 2009, the National Institute for Health and Care Excellence (NICE) undertook the development of a short clinical guideline to provide recommendations for the operation of milk banks and this was published in February 2010. The recommendations cover the operational aspects of human milk banking and the practical use of DBM within neonatal medical and surgical units include recommendations for the tracking and tracing of DHM. The guideline remains current with the date of the next review yet to be announced. The annual audit of compliance with NICE guidelines, as is mandatory for NHS Trusts, is an assurance process to ensure the relevant recommendations for both milk banks and neonatal and other units using DHM are being followed.

Legislation applicable to milk banks includes environmental health and food hygiene legislation however milk banks are currently not regulated in the UK. This is in common with milk banks throughout Europe with the exception of France, Italy and Slovakia. Where milk banks are organized as part of Tissue or Blood Banks the relevant EU Directives apply. The guideline produced by the British Dietetic Association on behalf of the Department of Health (due for publication) includes recommendations that also cover the handling, storage and use of DHM within hospitals.

Current recommendations on the use of DHM

The guideline relating to the establishment and operation of HMB within the UK, published by NICE, makes no recommendations about which infants should receive DHM. In the absence of national consensus, local networks (see *Appendices*) have often developed their own protocols and anecdotal feedback from individual NNU as well as usage figures from HMBs suggest there is currently marked heterogeneity in practice. This variability reflects the limited evidence base, and exemplifies the difficulties in producing nationally agreed guideline.

Several international health professional bodies including the World Health Organisation (WHO), American Academy of Pediatrics (AAP) and the European Society of Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) endorse the use of DHM whilst recognizing the limitations of the existing evidence. They recommend the use of DHM in preference to artificial formula milk in preterm infants when OMM is insufficient or unavailable, although the criteria for determining which preterm infants (i.e. based on gestation, birthweight or illness severity) are not well defined. Their recommendations emphasise the importance of supporting maternal lactation and only utilising DHM obtained from HMB operating to high standards. However, they are less specific about which categories of preterm infants should receive DHM and for how long. They all acknowledge the importance of further research into the short and long term health benefits of DHM as well as the economic implications of human milk banking.

Current usage of Donor Human Milk in the UK

The working group did not aim to collate guidelines for use from across the UK, but provide as an example guidelines from two HMBs (Greater Glasgow and Clyde and Imperial College NHS Trust, see appendices for details).

The extent to which DHM is used in the UK, including the variations in practice between NNUs and the rationale for its use, is not fully understood. A detailed analysis of the use of DHM on 2 NNUs (one level 3 and one level 2) both of which follow the Imperial College NHS Trust guideline for the use of DHM is presented in the appendices. The data for 2014 presented here is consistent with previously published data from the same NNUs (Weaver,

G. 2015) and provides evidence of use according to gestational age and birthweight in addition to details of the duration of use for over 400 infants.

In a recently published letter Zipitis et al (2014) present the results of a telephone survey of 211 UK NNUs. Their aim was to identify the use of DHM in the United Kingdom during 2013. Of the 95% of units which responded, 122 (61%) reported using DHM in the first few days (see map from paper – with this practice being reported most frequently in larger NICUs (75%). Only 67 units were able to provide information on the eligibility criteria for the initiation of DHM and the responses identified wide practice variability. In addition to prematurity, some units reported congenital gastrointestinal and cardiac anomalies as indications for use, whilst others also reported the use of DHM on the postnatal wards for term or near-term infants. The reported duration of use also varied markedly and ranged from 7-60 days (median three weeks' use). However, whether this correctly reflects actual duration is difficult to determine, as the letter makes no reference to whom they spoke and the appropriateness of that person to provide information on duration of DHM feeding. Of the 79 units responding who did not use DHM, around two thirds reported that cost was a major contributory factor in their lack of use, and around half reported access a key factor. Geographical spread across the UK varied with some regions appearing to have almost universal use (e.g. Scotland) and some regions reporting no usage (e.g. northern region of England).

Nutrient supply associated with DHM use

DHM has a lower density of several nutrients compared to OMM or artificial formula. Its use therefore needs to be balanced alongside the known benefits of achieving recommended nutrient intakes in preterm infants. This means that usage is commonly restricted to the time period when enteral feeds are being established, or in other high risk settings, such as following NEC, and where OMM is unavailable in sufficient volumes. Practice with regard to nutrient fortification of DHM e.g. with commercially available breast milk fortifiers (BMF), also varies between units. Randomised controlled trials of bovine-derived BMF have not been powered to determine any effects solely on NEC.

There is known to be marked variability in the macronutrient content of DHM. Recent literature suggests that it may be more nutritionally replete than previously believed (Wojcik et al, 2009, Cooper et al, 2013) but emerging techniques using proteomics show that key

proteins (particularly with immune properties) are substantially different following pasteurization. Many HMB now routinely perform macronutrient analysis on their donated milk, enabling targeted milk use and/or supplementation, a concept that is potentially appealing in situations when the neonatal gut is considered particularly vulnerable. In these situations, some clinicians consider it desirable that any further manipulation of milk is kept to a minimum. The protein content of all breast milk, mothers own as well as donor, is generally insufficient to meet the requirements of growing very preterm infants without fortification, but there remains substantial uncertainty as to the optimal growth velocity of preterm infants. Data from the Greater Glasgow and Clyde HMB indicated that even after the addition of a multi component breast milk fortifier only 61% of DHM samples would have achieved a protein intake of 3.5g/kg/day when fed at volumes of 180ml/kg/day (Cooper et al, 2013).

Practical issues associated with use of DHM

Although the risk is considered low, DHM is a biological product derived from other humans. This requires that very careful quality control procedures are used not only within HMBs, but also within NNU, including the ability to track and trace exposures should this prove necessary e.g. in the case of a donor who is subsequently diagnosed with a viral illness potentially transmittable via pasteurised breast milk. Occasional instances of incorrect administration (i.e. giving DHM to the 'wrong' infant) occur but are not considered to be high risk.

Current clinical uncertainties

Despite the current widespread use of DHM clinical uncertainties remain with a lack of high quality scientific data. The latter are required if a wider understanding of the uncertainties are to be provided to stakeholders. There is anecdotal evidence that DHM is being used in groups other than preterm infants, including term infants with congenital anomalies (e.g. gastroschisis, hypoplastic left heart syndrome), infants of mothers who are unable to breast feed for medical reasons (e.g. HIV, chemotherapy). In order to examine whether an evidence base exists for these practices, we (TW, NE, JS) carried out a search of five electronic databases to identify studies that might support the use of DHM in these groups.

Whilst the search strategy returned over 1000 results, we identified only one trial (currently in progress- NCT02025478) which aims to compare DHM to conventional feeds in children undergoing bone marrow transplantation. The working group also wished to highlight that use of DHM is relevant in healthcare settings where BAPM members may not always be well represented e.g. paediatric and cardiac intensive care, and other wards caring for infants following paediatric surgery.

We provide here a brief list of common clinical uncertainties highly relevant to the use of DHM that arose in discussions of the working group, but have included additional areas in the appendices. Overall, we were unable to identify any high quality (trial or observational) data, although it seems likely that the following issues are frequently encountered in UK NNUs such as:

1. **Populations of preterm infants 'eligible' to receive DHM**. Whilst most units currently using DHM agree that all infants <28 weeks should receive DHM (if insufficient OMM) there is no consensus about the upper gestational, birth weight or other risk-factor (e.g. presence of IUGR) cut-off. This reflects a lack of scientific data.
2. **Initiating oral feeds**. If the mother wishes to provide OMM but produces no milk, or only small amounts over the first few days when should DHM first be used? Some units start on day one and others not until day four.
3. **Nutrient adequacy**. DHM currently available in the UK will often not meet the nutrient needs, particularly the protein requirements, of preterm infants <32 weeks even when fed at volumes of 200ml/kg/day. There is strong evidence that inadequate nutrient supply in early life impacts adversely on later cognition, yet the optimal pattern of growth (or rate of weight gain) is not clear.
4. **Timing or use of breast milk fortifier (BMF).** If an infant is predominantly or exclusively fed on DHM should a BMF be used to improve nutrient supply, and if so when should it be commenced? Is it 'better' to feed a baby with DHM supplemented with BMF, or use an artificial milk formula once full feeds are established? How long should enteral feeds be tolerated before BMF is introduced?
5. **Duration of DHM use.** If a baby is receiving DHM, should this be continued until a specific postnatal or post-menstrual age, or should use be determined according to the presence/absence of specific risk factors? If OMM supply is insufficient when is the optimal time to transition to an artificial milk formula?

There are now 3 studies from the US describing the use of human breast-milk derived products including milks and fortifiers. The group felt that a discussion of this type of product was beyond our ToR but this highlights the need for a continual reappraisal of optimal current practice as new evidence and technical advances emerge.

Does the availability of DHM impact on provision of own mother's milk (OMM)?

A frequently raised concern, however, is that the *introduction* of DHM to a NNU might lead to a decrease in the use of OMM. To address this issue we conducted a systematic review (TW, JS, NE), and used an evidence mapping process, to scope the literature and refine a question in collaboration with the working group. The question was framed as "in mothers with infants admitted to a neonatal unit (Population), what are the effects of using donor expressed breast milk (Intervention) versus formula milk (Comparison) on maternal breast feeding rates in, and on discharge from, the neonatal unit (Outcome)." We searched seven electronic databases, emailed recognised experts in the fields of neonatal nutrition and use of DHM worldwide to identify any further references, and citation searched the references that met the inclusion criteria to identify a total of 10 studies. Six of these were papers were published in peer reviewed journals, and 4 were conference abstracts.

Interpretation of the data was limited by heterogeneity of patient groups and definitions of the use of maternal breast milk. Pooled data showed a significant increase in any breastfeeding on discharge after the introduction of DHM (RR 1.19, CI 1.06-1.35, p=0.005; data from 4 studies) but no significant difference on the rates of exclusive breast feeding on discharge (data from 2 studies) or exclusive breast feeding in the first 28 days of life (data from 2 studies). With a total of 2346 infants included in the 10 studies, we (TW, NE, JS) consider that a reasonable interpretation is that based on current evidence and practice, the introduction of donor milk to a neonatal unit does not adversely affect maternal breast feeding rates. However, one study from the United States (Esquerra-Zwiers A, et al. *Impact of Donor Human Milk in a High Mother's Own Milk Feeding Neonatal Intensive Care Unit*. International Society of Research in Human Milk and Lactation 2014) showed that the introduction of DHM was associated with a significant decrease in the percentage of feeds which were OMM in days 1-14 ($p<0.01$) and days 1-28 ($p=0.04$) of life. Interestingly, correspondence with the authors of this study showed that after a change of policy in how

DHM was used in practice (by delaying introducing the idea of DHM to mothers to at least 48hrs post-birth) there was an improvement in the OMM rates in the post-DHM group compared to the pre-DHM group. This further confirms that the introduction (or use) of DHM is a complex intervention where effects are likely to differ between populations and healthcare settings.

Parental perspectives

The working group received a presentation from Stephanie Tempest (Senior Lecturer, Brunel University) who reported on a recent survey of parental attitudes to the use of DHM. http://www.ukaHMB.org/2014/02/15/what-do-you-think-of-uk-milk-banking/

Further information will be available in publications but a number of key points are detailed below:

1. Advice and encouragement from health professionals and peers are more powerful than advertising;
2. The main respondents to the survey were from breast-feeding non-milk-donor mothers i.e. they were potential donors of breast milk;
3. The importance of normalizing the image of breast-feeding and DHM;
4. The ability to donate can potentially help some bereaved mothers;
5. The potential benefits of defining national eligibility criteria for the use of DHM.

There is considerable discussion amongst parents on the issue of DHM. You can find further information relating to the typical questions parents ask, and how to answer them, on the website of the UK Association for Milk Banking http://www.ukamb.org/info-for-hcps/speaking-to-parents-of-prems/.

Information resources for parents

There is a limited range of resources available for parents on the use of DHM. The resources that exist relate almost exclusively to the actual donation of milk rather than for parents whose child is in receipt of DHM. Most milk banks within the UK have either developed their own range of parental literature, or access the Health Care Professional leaflets produced by the UKAMB. A number of websites provide a limited amount of

information for parents (see appendix), many of which direct parents to the information available from the UKAMB Website – www.ukamb.org

Other secure sources of information are available from groups such as Bliss, which has information on its website at www.bliss.org.uk as well as producing a range of printed materials, and also offers access to peer support through its online forum hosted with Netmums http://www.netmums.com/coffeehouse/advice-support-40/premature-scbu-babies-564/; and Best Beginnings, which has produced the Small Wonders DVD http://www.bestbeginnings.org.uk/small-wonders which discusses the work of milk banks and the availability of DHM.

Numerous websites provide information and access to informal milk sharing, or where opportunities are given for the purchase of DHM. Facebook is also widely utilized between parents for the informal sharing of DHM (http://www.facebook.com Human Milk 4 Human babies and Eats on Feets). The existence and influence of these resource sites should be acknowledged by health professionals and parents supported in making informed decisions regarding milk sharing. A joint statement, published in 2015 by the European Milk Bank Association (EMBA – www.europeanmilkbanking.com) and the Human Milk Bank Association of North America (HMBANA – www.hmbana.org) has been adopted by the UKAMB. It can be viewed via the EMBA website. This emphasises the risks of informal milk sharing to the baby, and the potential to adversely impact on milk supply to donor milk banks.

There may be dangers associated with parents being unable to access DHM if they believe it is 'good' for their baby. There are several reports of mothers accessing breast milk using the internet (rather than through approved milk banks). This milk is of uncertain quality and is unlikely to have been screened for infectious agents. In addition, a recent report identified that around 10% of milk samples purchased in the US via the 'Only The Breast' website on which women sell their milk had cow's milk deliberately added, presumably to increase the volume (Keim et al. Pediatrics 2015).

Cultural issues relating to DHM

Whilst DHM is in general acceptable to the vast majority of parents, there are certain groups to whom the use of DHM could be potentially problematic. A survey of UK milk banks showed that over two thirds were aware of instances where DHM had been initially refused by Muslim parents although this was happening infrequently (Donor Human Milk for Infants of Muslim Parents. European Society for Paediatric Research Annual Conference, Porto, Portugal 2013). This may be due, in part, to the Islamic concept of milk kinship, whereby recipients of DHM are believed to become related to the family of the donor (see also http://www.ukamb.org/info-for-hcps/dhm-for-infants-of-muslim-parents/). However, this is a complex area and beyond the scope of this current framework document. In some cases, after discussion with religious leaders, the decision made is that in the interest of the principle of preserving life it is acceptable to use anonymised DHM. In summary, some religious organisations may have views on the use of DHM that differ to those of the clinical team. In these situations liaison with a local religious lead may help resolve any differences, emphasising the importance of considering each baby individually when making decisions about neonatal care. As a result of this working group, a meeting and subsequent correspondence between BAPM (TW), UKAMB (GW), a representative from the Muslim Council of Britain (Dr Shafi), Muslim scholars and others took place in 2015. A resolution which continues to allow for the provision of DHM to Muslim families was reached, and this was shared with BAPM at the forthcoming AGM (see appendices). A recommendation was made that there is a need for a robust system to ensure the traceability of donated milk.

The working group also considered that a national support organisation such as Bliss could consider providing information on a website that addressed several of the cultural issues relevant to neonatal practice that might include:

1. web-links or contact information for religious organizations or committees;
2. a brief summary of current understanding or common approaches including information for specific groups of parents.

Conclusions and recommendations

Current usage of pasteurised DHM varies across the UK and is not universal. The availability of DHM may have an, as yet unquantified impact on maternal breast feeding rates. Both positive and negative impacts of DHM have been reported.

The existing evidence has not raised safety concerns regarding use of DHM, but evidence of efficacy is currently inadequate to make firm recommendations for use. There may be neuro-cognitive (or other) benefits from DHM but it is also possible that inadequate nutrient provision with DHM adversely impacts on longer term cognition.

Provision of DHM across the UK lacks a coordinated approach, reflecting at least in part an inadequate evidence base. Evidence regarding both clinical and cost-effectiveness is urgently needed to determine indications for use of DHM.

We strongly support a need for further research in this field as a national priority, including determining both short and longer term effects for baby and mother, wider societal effects and careful health economic evaluation.

If DHM is shown to be of benefit, universal access at a national level across the UK will require a safe and sustainable infrastructure for supply, processing, and delivery. Funding will need to be identified, and the process supported by robust auditing of practice.

In the absence of high quality data, individual networks and hospitals should continue to develop their own policies and procedures for the use of DHM recognising that there is insufficient evidence to recommend the universal adoption of DHM. Stakeholders need to be aware that some clinicians, parents, and parental and user groups hold strong opinions, which will need to be taken into account when designing clinical trials. NNUs and clinicians should be encouraged to participate in high quality research to bring about rapid resolution of important, continuing uncertainties in the use of DHM.

Appendix 1

Scotland wide human milk bank – a case study

History

The original and only human milk bank (HMB) in Scotland opened in 1978 at the Queen Mother's Hospital, Glasgow. In addition to providing milk to preterm babies in the maternity hospital the bank supplied milk to more mature post-operative infants in the co-located Royal Hospital for Sick Children (RHSC). The HMB had no dedicated staff at this time and handled milk from 8 to 12 donors annually. The donated milk was pasteurized in the RHSC "milk kitchen" prior to administration to around 8 to 16 babies annually.

Concerns regarding the regulatory standards of the HMB were raised by Scotland's Chief Medical Officer in 2006. In response to these concerns the Scottish Government provided funding to support a two year temporary post to upgrade the service and ensure equity of access to milk across the health board.

As a consequence of increased access to and awareness of donor human expressed breast milk (DHM) within the local health board there was an escalation in interest from neighbouring Scottish health boards, resulting in frequent informal requests for DHM. This increase in demand coincided with significant service expansion from 2009 onwards, both in the processing of donated milk and the numbers of babies who received milk.

Development of a Scotland Wide Service Model

As the service evolved and developed, competing staff priorities and a lack of structure to support the growth proved challenging. The level of external interest, both from NHS staff in other health boards and parents was becoming unmanageable and there was increasing recognition that we had to address the issue of equity of access across the country as a whole.

Until 2011, there was no infrastructure to move DHM easily and safely between neighbouring health boards. *ScotsERVS*, a local medical transport charity, was able to address this need by providing a responsive and reliable mechanism for transporting milk. In addition many donors were from out with our local health board, requiring our local milk bank

coordinator to travel extensively to support donor screening. This model was inefficient both in terms of time and expense.

In August 2012, NHS Greater Glasgow and Clyde (NHS GGC) hosted a Scottish wide event to facilitate discussion of DHM provision in Scotland. There was representation from all Scottish boards and all options were fully appraised including;

1. Retain the status quo
2. A hub and spokes model with a central bank and several peripheral milk “depots”
3. A single site HMB hosted by one board but paid for and accessed by all boards

The majority of health boards opted for a single site milk bank, essentially to capture the existing infrastructure and expertise and to ensure safe, cost effective and equitable milk provision.

Funding a single site HMB was a little contentious. Several local health boards have no tertiary neonatal facilities yet their babies might access DHM in their regional neonatal unit. To ensure that this was captured it was agreed that each health board should fund a pro rata share of the costs based on their adjusted birth rates. This option was felt to offer a more sustainable income stream than the cost per litre option used by many international HMB. Charitable funding was used in the relocation to a larger refurbished premise and in June 2013 the Scotland wide service was officially launched.

Wider Perspective

In order to achieve the recommendations within the NICE Clinical guideline the NHS GGC HMB in conjunction with the Scottish National Blood Transfusion Service (SNBTS) developed a milk management system. As a result of the developmental work undertaken at NHS GGC HMB on the milk management system it became apparent there was no standardized labeling procedure for DHM. *ICCBBA* (www.iccbba.org) who manage, develop and license *ISBT 128*--the international information standard for blood, cell, and tissue coding and labeling, agreed to a pilot implementation at NHS GGC HMB and this has led to the formation of the Milk Banking Technical Advisory Group (MBTAG) who are working on a standardized nomenclature for human milk products which has been endorsed globally.

Greater Glasgow and Clyde HMB guidelines for DHM usage

1. In the absence of OMM, DHM will generally be the milk of choice for establishing enteral feeds in neonates at “high risk” of developing NEC i.e.
    - <28 weeks gestation
    - Birth weight <1000 grams
    - <32 weeks gestation plus intra uterine growth restriction [weight <9th percentile and abnormal antenatal Doppler’s (absent / reversed end diastolic flow)]
    - Previous proven NEC ± laparotomy
    - Post GI surgery
    - Congenital heart disease with potential for gut hypoperfusion e.g. hypoplastic left heart syndrome
2. DHM has a relatively poor nutritional profile and so its use should be restricted to either establishing feeds in high risk infants when OMM is unavailable or for the short term support of a preterm infant whose mother is establishing milk expression. DHM is not routinely fortified and once volumes of 180-200ml/kg are tolerated infants should be gradually weaned to an appropriate formula.

Appendix 2. The Milk Bank at Queen Charlotte's and Chelsea Hospital

2A
The Milk Bank at Queen Charlotte's and Chelsea Hospital - a case study

The Milk Bank at Queen Charlotte's and Chelsea Hospital (QCCH) has a long history of milk banking dating back over 75 years. It is the longest continually operating milk bank in the world. It was officially established in 1939 and was the first functioning milk bank in the UK. November 2015 will see the 80th birthday of the set of quadruplets whose birth and subsequent feeding with breastmilk collected from mothers at Queen Charlotte's Hospital led to the later establishment of the milk bank (Williams AS 1997). The quads are all alive and well and looking forward to their 80th birthday celebrations.

The attached Infant Journal article *'Under the Spotlight: The Queen Charlotte's Hospital Milk Bank at 75'* from January 2015 details the history and current activity of the bank which routinely supplies DHM to both of the Imperial College Healthcare NHS Trust (ICHNT) neonatal units in addition to approximately 20 external units per year. The ad hoc external provision of milk varies from once or twice per year to at least monthly, demonstrating the differences in provision (and so use of DHM) to NNUs, even those within close proximity to each other.
The units using the most DHM are those belonging to the Imperial College Healthcare NHS Trust where the availability and use of readily accessible supplies of DHM are closely monitored to ensure that they do not undermine support for mothers to quickly provide their own colostrum and to maintain their lactation and so supply their own breastmilk. (See guideline for use – Appendix B). A summary of the activity of the QCCH milk bank in the calendar year 2014 follows.

Staffing
Throughout 2014, the Milk Bank at QCCH was staffed by a full time manager, a 0.8 WTE part time administrator and a 0.5 WTE technical and laboratory assistant. The Trust also benefited throughout 2014 from the regular contributions of 3 volunteers; a retired accountant, a medical student and a neonatal nurse/breastfeeding specialist.

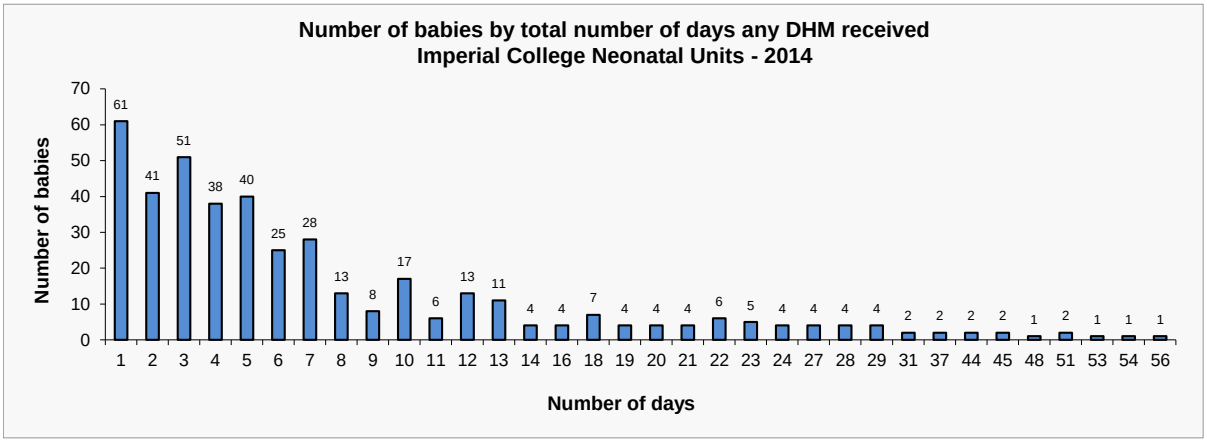
Breastmilk Donation
Breastmilk donors fall into two main categories – the majority are mothers who express milk for donation on a daily basis and freeze and store their milk at home prior to its collection. However donor human milk (DHM) also comes from a smaller group of donors who have stored their breastmilk whilst their infant (usually born preterm) has been cared for on a neonatal unit. When their infant is discharged fully breastfeeding some mothers choose to donate their stored breastmilk to the Milk Bank. Bereaved mothers are also often recruited as donors. During 2014, 136 mothers were fully recruited as donors having undergone the screening and serology tests recommended by NICE in Clinical Guideline 93 (NICE 2010) and went on to donate their milk.

Transporting DHM
The milk bank benefits from the services of volunteer motorcyclists provided by SERV (Service by Emergency Rider Volunteers) who collect donor milk from mothers' homes and deliver it to the milk bank in addition to delivering milk from the milk bank to other hospital neonatal units. The services of three SERV groups are regularly used covering most of the areas to the north, south and west of London. Their services are provided free to the Trust and to hospitals being supplied by the Milk Bank and they are helping to ease the logistical

difficulties posed by a growing number of mothers wanting to donate their milk and a growing number of hospitals wanting to access donor milk.

Use of DHM

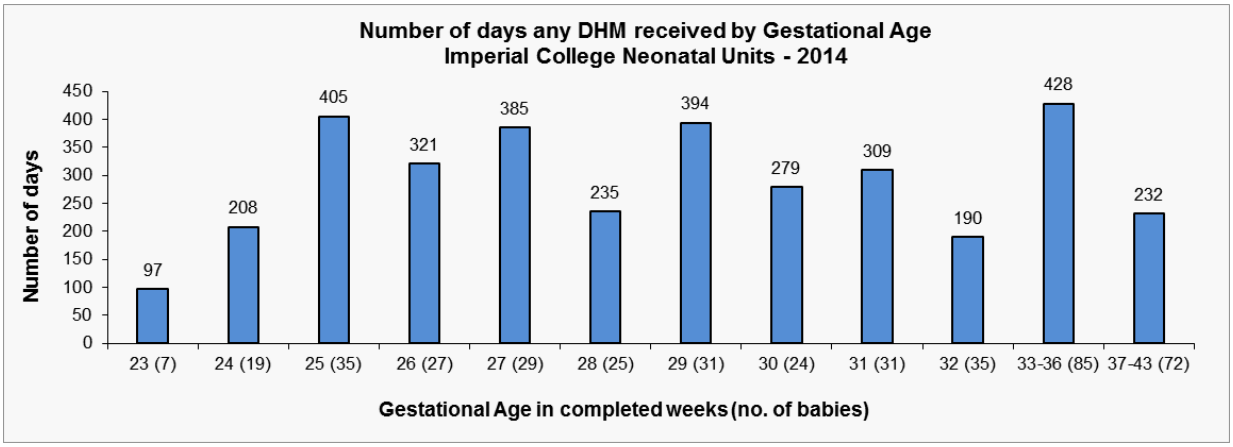
During 2014, 420 babies admitted to Imperial College Healthcare NHS Trusts (ICHNT) neonatal units received DHM. (See figure below). DHM was mainly used to supplement the mother's own milk and most babies required DHM for relatively short periods of time. DHM was required for 5 days or less in 55% of babies, 7 days or less in 68% of babies and for 14 days or less in 85% of babies.

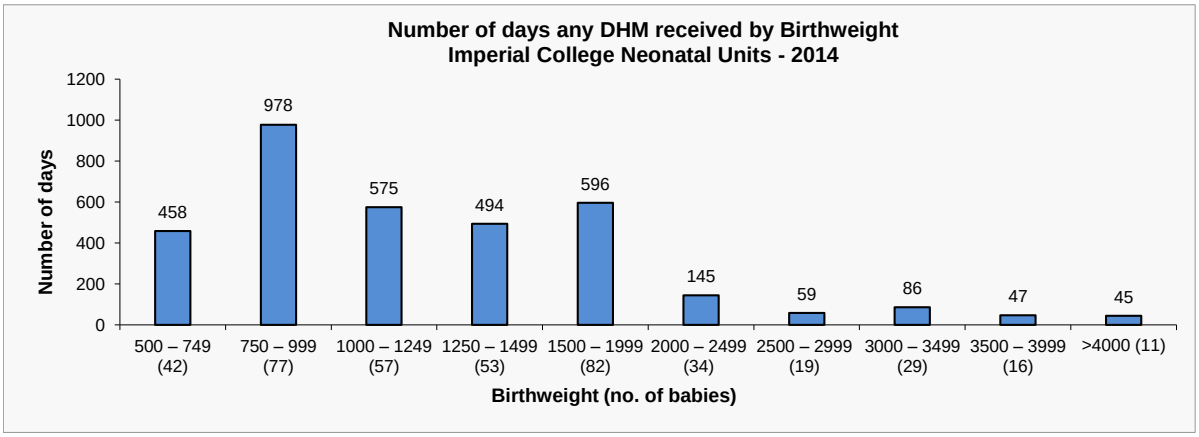


The total number of feeding days for the infants who received breastmilk (donor and/or maternal) in 2014 was 11,084 and of these on 69% of days babies received exclusive maternal human milk (MHM) feeds, on 13% of days babies received exclusive DHM feeds and on 19% of days babies received mixed of DHM and MHM feeds.

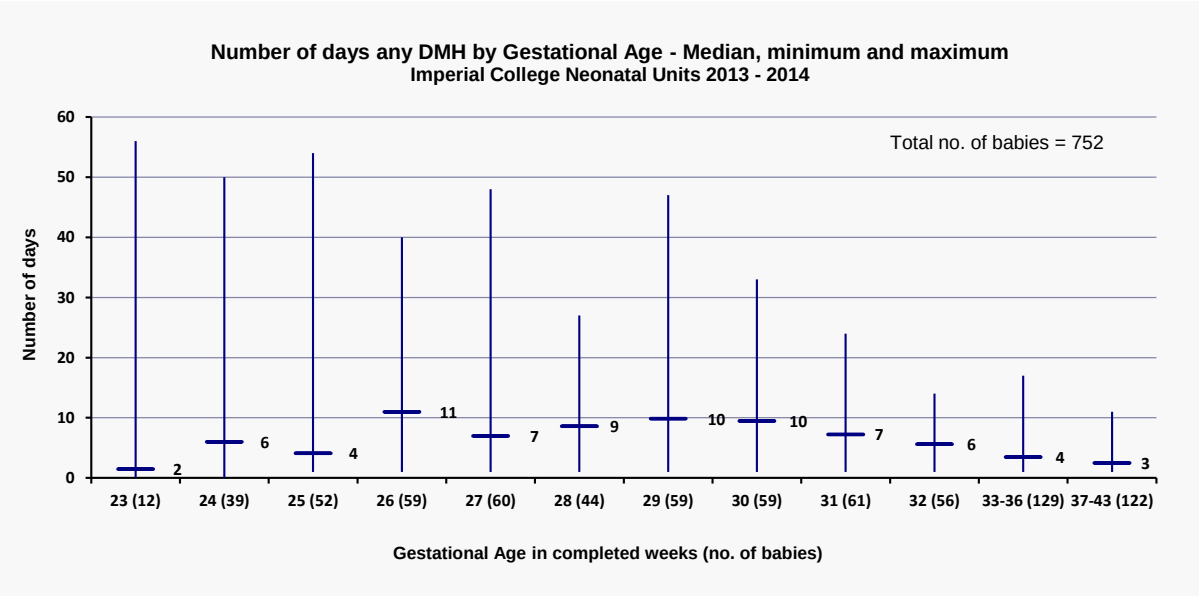
The volume of pasteurised DHM issued from the milk bank for the year 2014 was 734 litres (up from 509 litres in 2013, and 414 litres in 2012) of which 478 litres was used by ICHNT neonatal units (290 litres in 2013).

Figures below show the number of days infants received DHM at ICHNT Neonatal Units analysed according to birthweight and gestational age.





The median, maximum and minimum number of days shows the variable length of time over babies may require DBM, despite mothers receiving high quality, consistent support to help them provide their own milk for their babies. This serves to illustrate the importance of having ready and easy access to DBM.



A clinical audit performed during 2013 showed that the wider use of DHM could be supported by the Milk Bank and a revised protocol for the clinical use of DHM was agreed at the end of the year. The figures for the provision of DHM during 2014 represent the usage for the first full year following the introduction of the revised guideline and demonstrate that the increased demand could be fully met by the milk bank.

Neonatal units throughout London, Hertfordshire and Sussex regularly received DHM from the QCCH bank during 2014 with a total of 21 units supplied with DHM throughout the year.

Research

The milk bank continued to support clinical and nonclinical research and throughout 2014 collaborated with Imperial College, London Metropolitan and Brunel (London) Universities.

Breastmilk that does not meet the strict standards required to be issued as a feed for babies and which would otherwise be discarded may be made available for research purposes (with donor consent). It is stored in a freezer that is registered with the Imperial College Tissue Bank and all research milk samples are entered onto the Tissue Bank database. In addition research looking at the profiles, experiences and perceptions of donors has been supported and facilitated by the milk bank.

Milk bank manager Gillian Weaver is the current President of the European Milk Bank Association (EMBA[2]). The term of office is 2012 – 2015. From 2010 - 2015 Gillian also led the UK Association for Milk Banking's (UKAMB[3]) National Milk Bank Forum which provides training events for milk bank staff.

Acknowledgments
Thank you to Graham Parish and Barry Philips for their assistance in providing the data on the use of DHM on the neonatal units, to the mothers who freely donated their breastmilk and to all colleagues who actively supported the continued growth in productivity within the milk bank throughout 2014.

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- Williams AS, Women and Childbirth in the Twentieth Century Sutton Publishing Ltd 1997 ISBN 0 7509 1209
- NICE Clinical Guideline 93; Donor Milk Banks; the operation of donor milk bank services http://www.nice.org.uk/guidance/cg93
- EMBA www.europeanmilkbanking.com
- UKAMB www.ukamb.org

Appendix 2B

Imperial College Healthcare NHS Trust

Neonatal Service

THE USE OF DONOR BREASTMILK AT IMPERIAL COLLEGE HEALTHCARE NHS TRUST

Introduction

The best milk for babies is the mother's own breastmilk.
Every effort should be made to help mothers express their colostrum (early milk) as soon as possible following delivery, as this is the preferred trophic and enteral feed. (See Preterm Lactation and Breastfeeding Guideline.)

The availability of safe, screened and pasteurised donor breastmilk (DBM) from the Queen Charlotte's and Chelsea Hospital Milk Bank enables access to DBM as required according to the following guideline. However, when clinically indicated, pasteurised donor breastmilk (DBM) is the third choice when commencing enteral feeds except in the rare circumstances when maternal EBM cannot be used (eg maternal HIV infection).

Choice 1: Freshly expressed, raw maternal expressed breastmilk MEBM (refrigerated if expressed > 2 hours prior to feed)
Choice 2: Thawed frozen maternal EBM.
Choice 3: Thawed donor breastmilk from the Queen Charlotte's and Chelsea Hospital Milk Bank (Imperial College Healthcare NHS Trust). The ready availability of DBM should not undermine optimal support for a mother to express and collect her own colostrum and to initiate and maintain her lactation and achieve volumes of breastmilk (BM) that will enable her to be able to later fully breastfeed her infant(s).

Obtain informed consent for the use of DBM

Consent is required – the process for obtaining this is described elsewhere

Which babies should have donor breastmilk?

- All babies less than 32 weeks gestation at birth
- More mature babies who fit the criteria below

1. Post abdominal surgery/recovering from necrotising enterocolitis
2. All babies receiving Parenteral Nutrition
3. Consistently absent/reversed end diastolic flow
4. Intra Uterine Growth Restriction if birth weight less than 2nd centile
5. Babies requiring cooling treatments
6. Haemodynamically unstable babies who have required inotropic support
7. Babies born between 32 and 34 weeks where the mother wishes to exclusively breastfeed
8. Siblings of multiple pregnancy where one infant is receiving DBM as a result of meeting criteria 1 – 6

In the event of supplies being unavailable for all these babies the following should be prioritised:

- Babies < 27 weeks
- Post abdominal surgery / recovering from necrotising enterocolitis
- Consistently absent / reversed end diastolic flow
- Growth restriction below 2nd centile

How long to use for infants whose mothers plan to breastfeed

- In lower risk infants 32 – 34 weeks until day 5 post delivery
- In lower risk infants < 32 weeks – until full enteral feeds
- In high risk infants – for 1 – 3 weeks after full enteral feeds depending on clinical assessment, which must be determined for each baby individually
- If transfer is planned to another hospital which doesn't have a milk bank, inform milk bank staff as soon as possible to arrange to send up to 3 days' supply with the baby where available

Grading onto formula

- Start with ¼ formula for 24 hours
- Increase by ¼ every 24 hours as tolerated, ie regrading should take a minimum of 3 days

Breastmilk fortification may be required

Supplies of donor breastmilk

Milk bank staff will inform nurse in charge if supplies are low but otherwise assume ample supplies

Documentation

All individual containers of DBM are accompanied by spare matching ID labels, one of which should be placed on the feeding chart in the nursing notes alongside the feed documentation. The date and time and the name and hospital number of the recipient should also be documented on the DBM chart in the Milk Kitchen together with the name and signature of the nurse who decants each DBM feed.

Appendix 2C

The United Kingdom Association for Milk Banking (UKAMB) and audit data from the UK Milk Banks.

The UKAMB, which is a registered charity, was founded in 1997 to exchange information, provide training opportunities, review guidelines, promote research into human milk banking and the use of DHM and to support human milk banks (HMBs). The UKAMB Trustees and officials comprise milk bank staff, lactation experts, researchers and clinicians as well as service users.

A comprehensive audit of milk bank activity in England was undertaken in 2010 by Gillian Weaver. This involved a site visit to each bank to assess and compare facilities as well as to audit milk banking activity. It did not include the milk banks in Scotland or Northern Ireland. No milk banks operate in Wales; however several milk banks in England recruit donors from Wales and provide pasteurised DHM to neonatal units in Wales.

The data has been updated during 2015 and now includes the milk banks in Scotland and Northern Ireland and details of activity for 2012 – 2014. During this time the number of HMB decreased from 17 in 2013, to 15 in 2014 following the merger of two HMBs in the North West of England and two in the South East. This work identifies that a clear disparity exists between banks in terms of staffing (including hours worked, staff training and development opportunities and staff pay bands), physical space, facilities and equipment. However, despite this the recruitment of donors, volumes of raw milk collected and pasteurised milk issued from the UK's banks continues to rise year on year.

The activity and the running costs of each bank vary. There are several different operational and staffing models; a review of these is not within the scope of this framework. Volunteer help is available in some banks and supports a wide range of milk banking activities. Every milk bank requires essential pasteurisation equipment and this accounts for the greatest capital outlay at between £6,000 and £20,000 per machine. The extent to which this is in daily use differs and in small banks may only be in operation once or twice a week. Sufficient space to safely process and store DHM is also essential.

The number of donors recruited by each HMB in 2014 ranged from 26 to 248; two thirds of banks consistently recruited less than 100 donors per year. The volume of raw human milk collected by each bank in 2014 ranged from less than 50 litres to 2000 litres; 13 out of 17 HMBs collected less than 1000 litres. Following microbiological testing, inevitably some milk is discarded. The percentage of milk failing bacteriology testing also differs widely between banks and this merits further investigation. The volume of pasteurised DHM issued by individual banks in 2014 ranged from 21 litres to 1750 litres; over half of the banks issued less than 500 litres. Finally all but 2 milk banks provided DHM to external neonatal units and surgical units. The number of units / hospitals supplied varies widely, as does the frequency of provision (from occasionally to weekly/monthly). The HMB in Northern Ireland also supplies DHM to 16 hospitals in Eire.

The total volume of DHM available throughout the UK has increased from 5000 litres in 2012 to 7000 litres in 2014, with a year on year increase in output from all but 2 of the banks that provided complete data sets. The volume processed may seem large however, if this DHM was used exclusively to feed the babies born each year in the UK below <30 weeks that

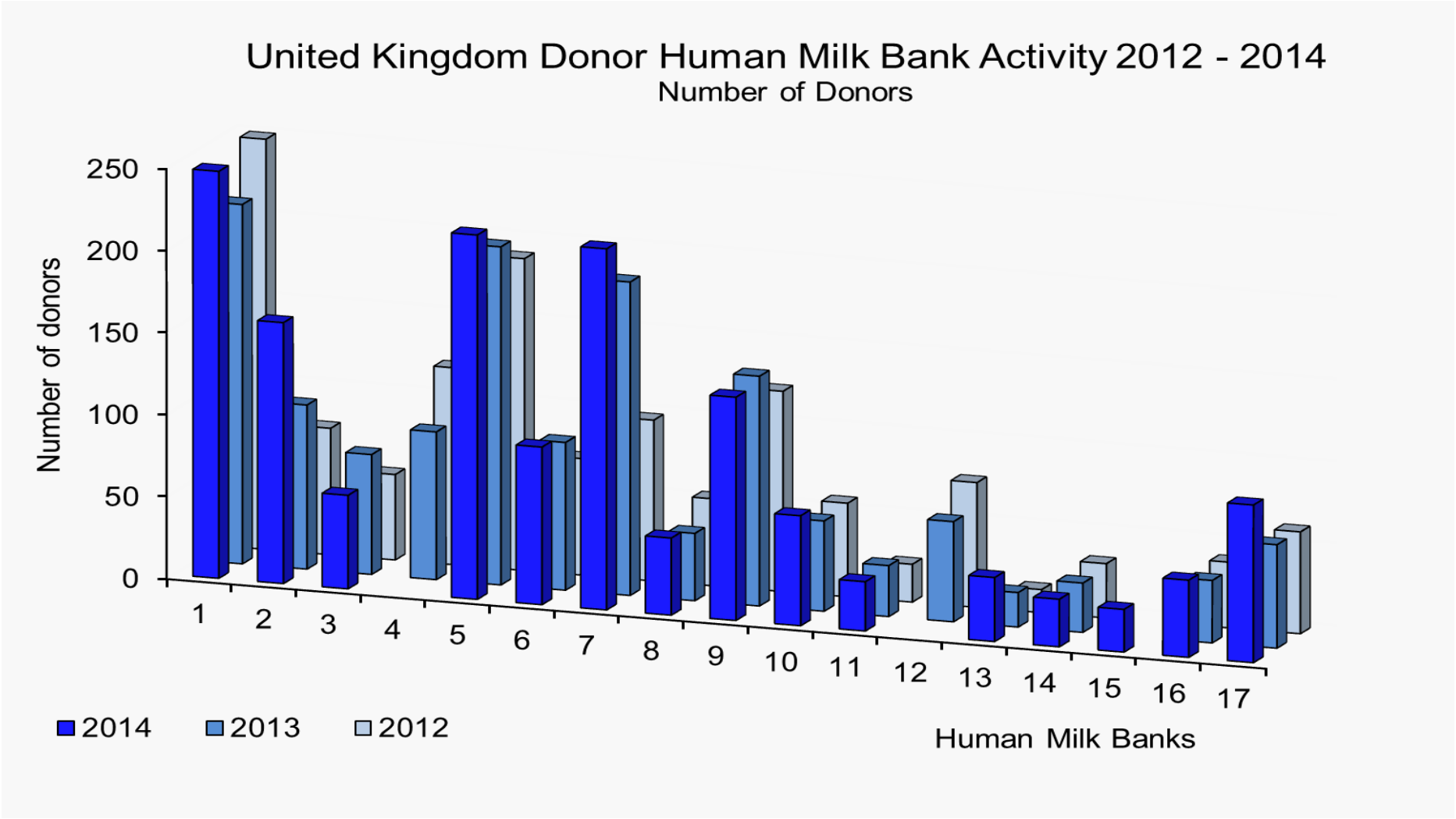
equates to just 1.6 litres per baby. Babies of this gestational age range require an average of 650mls to establish full enteral feeds, this leaves only enough milk to provide feeds for these babies at 150ml/kg for 7 days.

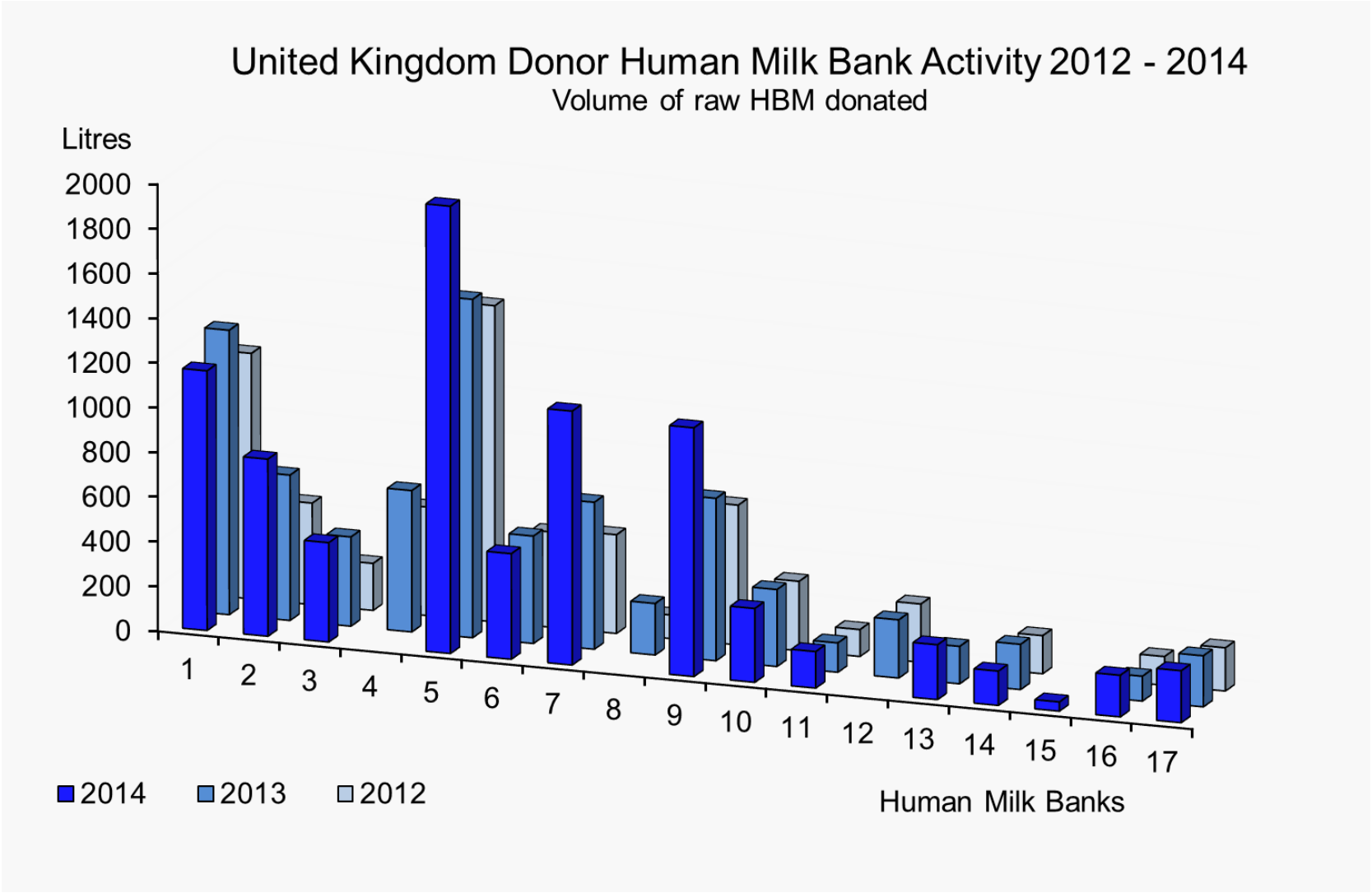
Most milk banks in England supplying DHM to external NNUs make a charge to cover some of the processing costs. The remaining costs are mostly frequently born by the Trust hosting the milk bank. The charge varies between £100 and £200 per litre (i.e. between £5 and £10 per 50mls). This in turn equates to a cost of £160 - £320 at a volume of 1600mls per infant if used to enable most preterm infants born at <29 weeks to establish feeds.

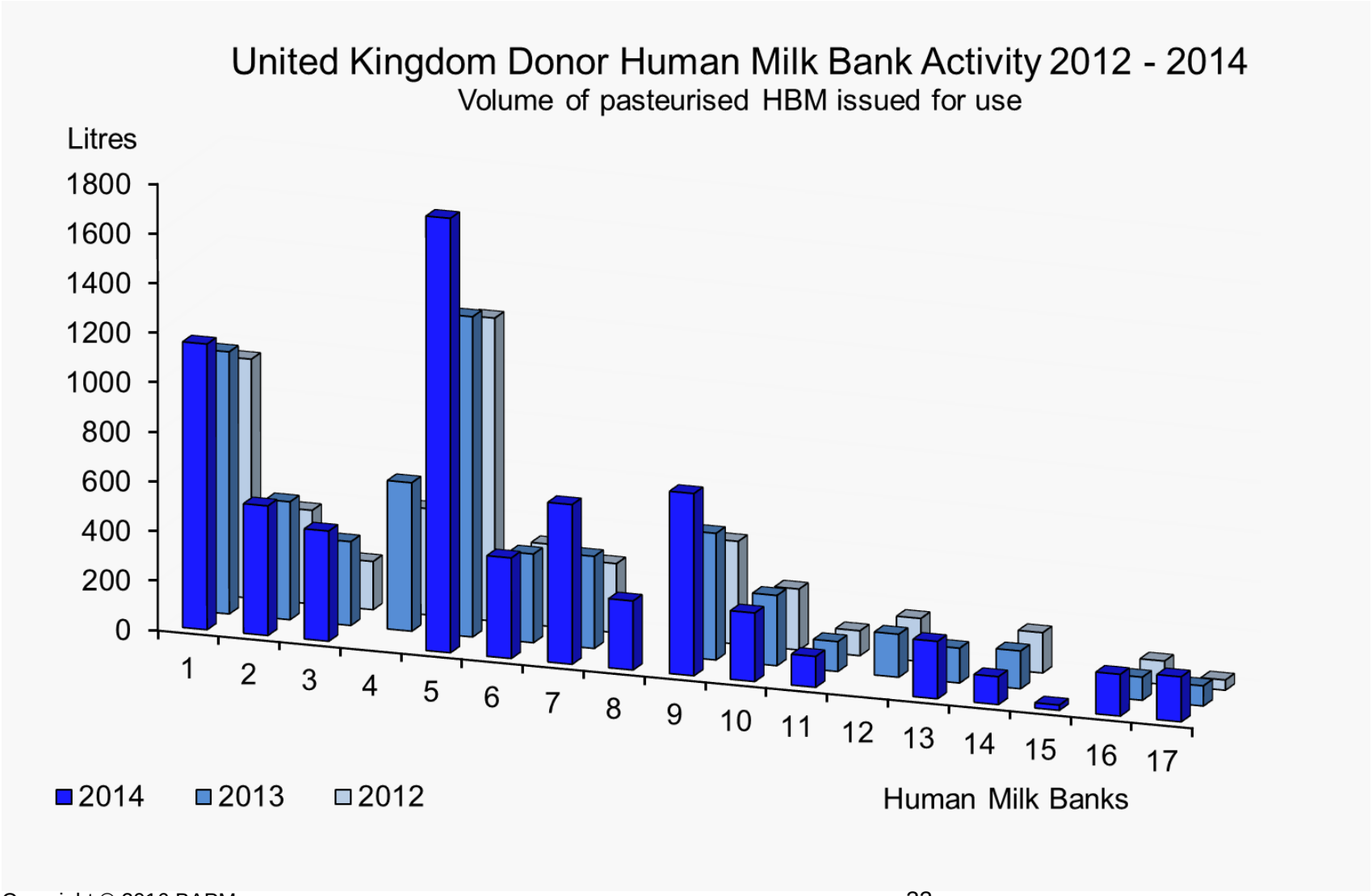
The tracking of DHM through each UK milk bank and its traceability is still largely dependent on paper records. Electronic barcode systems specifically designed for DHM and HMBs, including a Cloud based system, are in development or currently available. International coding for breastmilk using the standard ISBT128 has been developed by ICCBBA (International Council for Commonality in Blood Banking Automation) and agreed following global consultation.

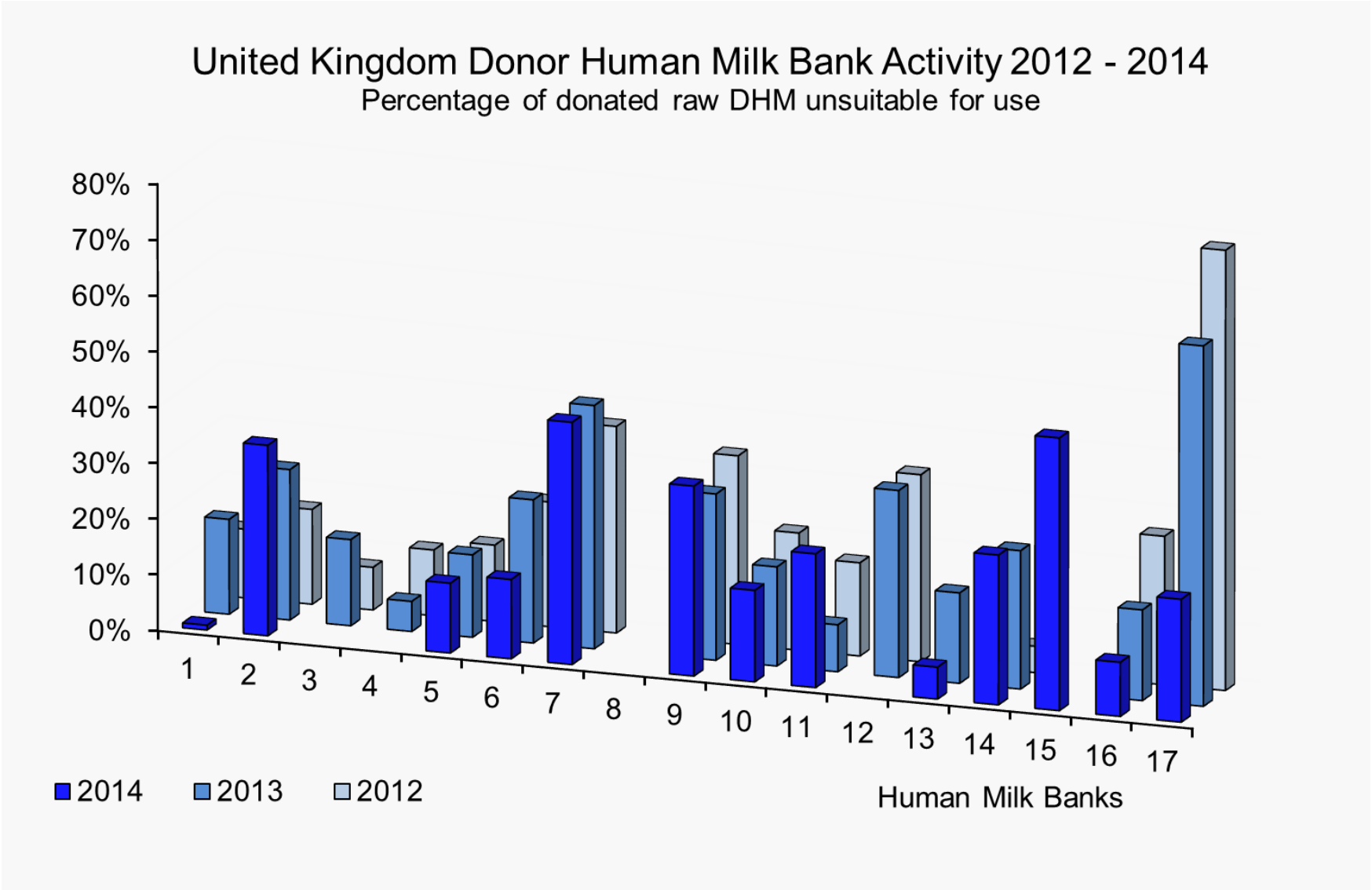
There is currently no external accreditation of milk banks and there are no certificated or nationally accredited training opportunities for milk bank staff. The charity, the UK Association for Milk Banking (UKAMB) facilitated the accreditation of milk banks against a set of standards based on the UKAMB national milk bank guideline *(Guidelines for the Establishment & Operation of Human Milk Banks in the UK (3rd edition 2003) UKAMB, endorsed by RCPCH)* however this ceased in 2010 once the NICE guideline was published. All NHS Trusts are routinely audited against the recommendations set out in NICE guidelines, and so, this is the route whereby HMBs are currently accountable for any unmet recommendations. However HMBs are exempt from the EU Tissue Banking Directive *(Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells)* and are therefore not currently routinely inspected against any national standards.

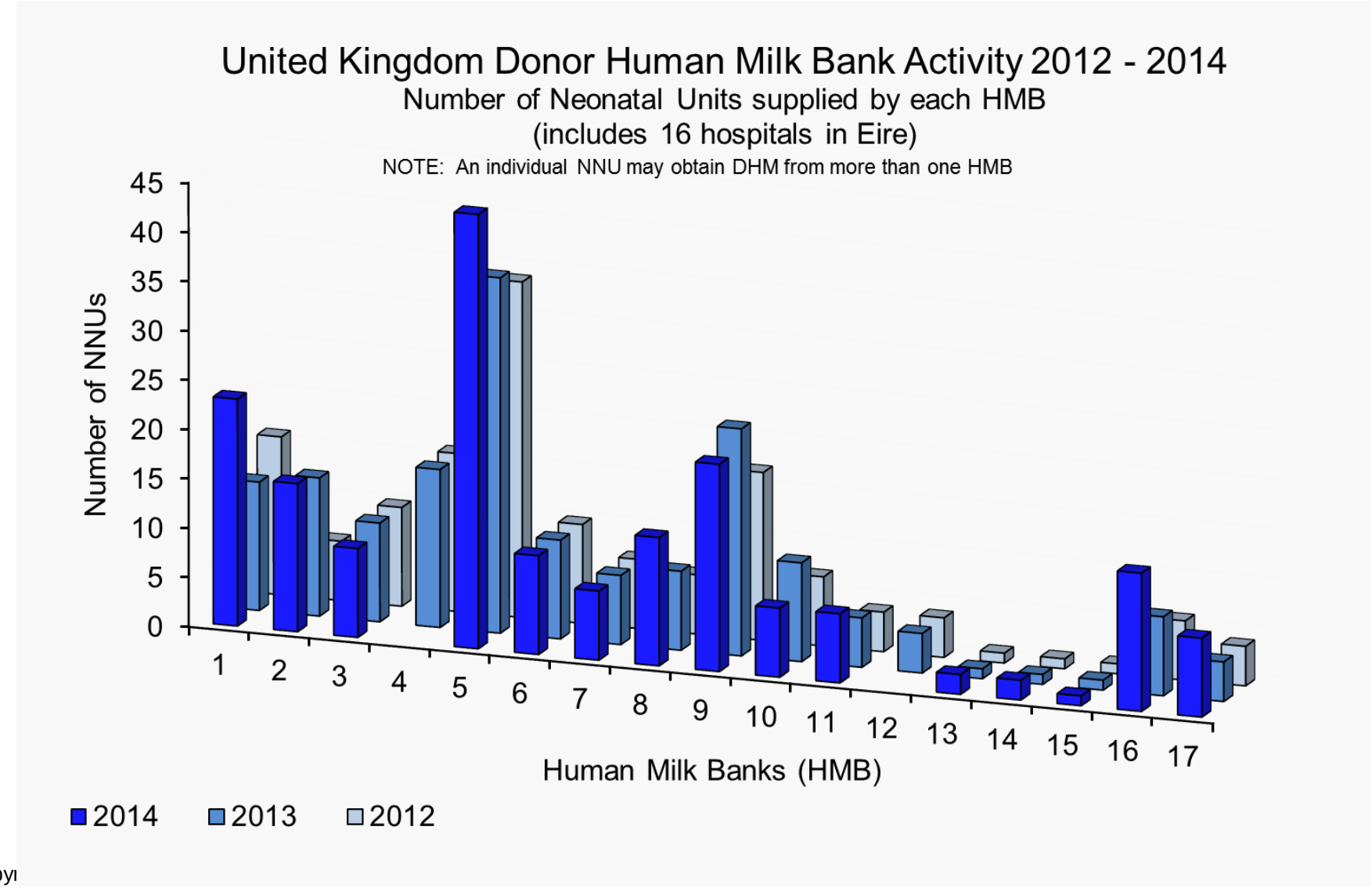
UKAMB regularly (usually twice a year) provides training opportunities that are free of charge or greatly subsidised for milk bank, dietetic and neonatal unit staff. These are designed to provide updates and training on a wide range of milk bank related topics and are held around the UK to facilitate attendance. The development of suitable online training modules for milk bank staff is currently being explored by Department of Health Sciences staff at Brunel University and it is hoped that this will lead to the availability of routinely adopted, certificated updates for all milk bank staff working in the UK.

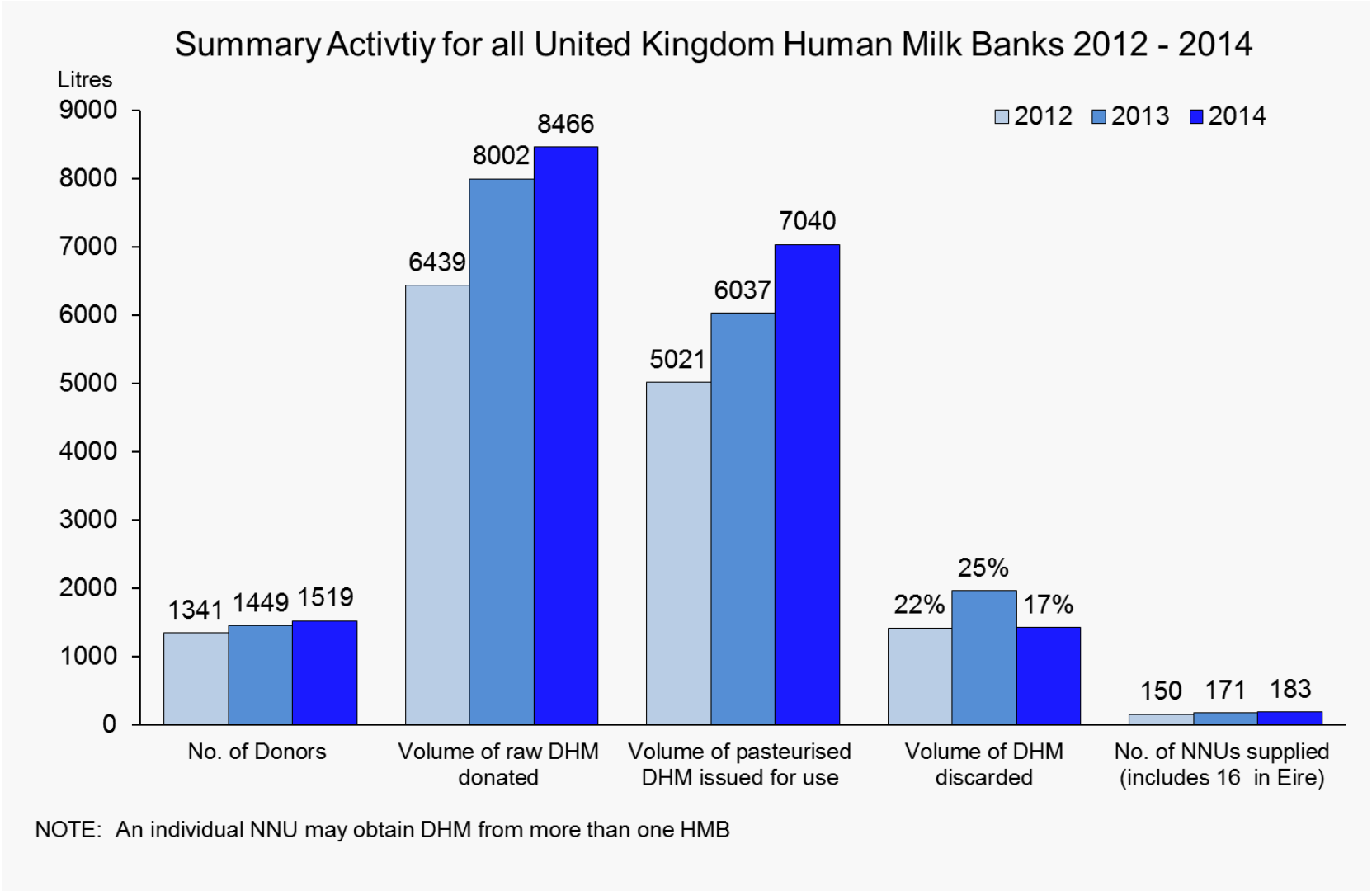


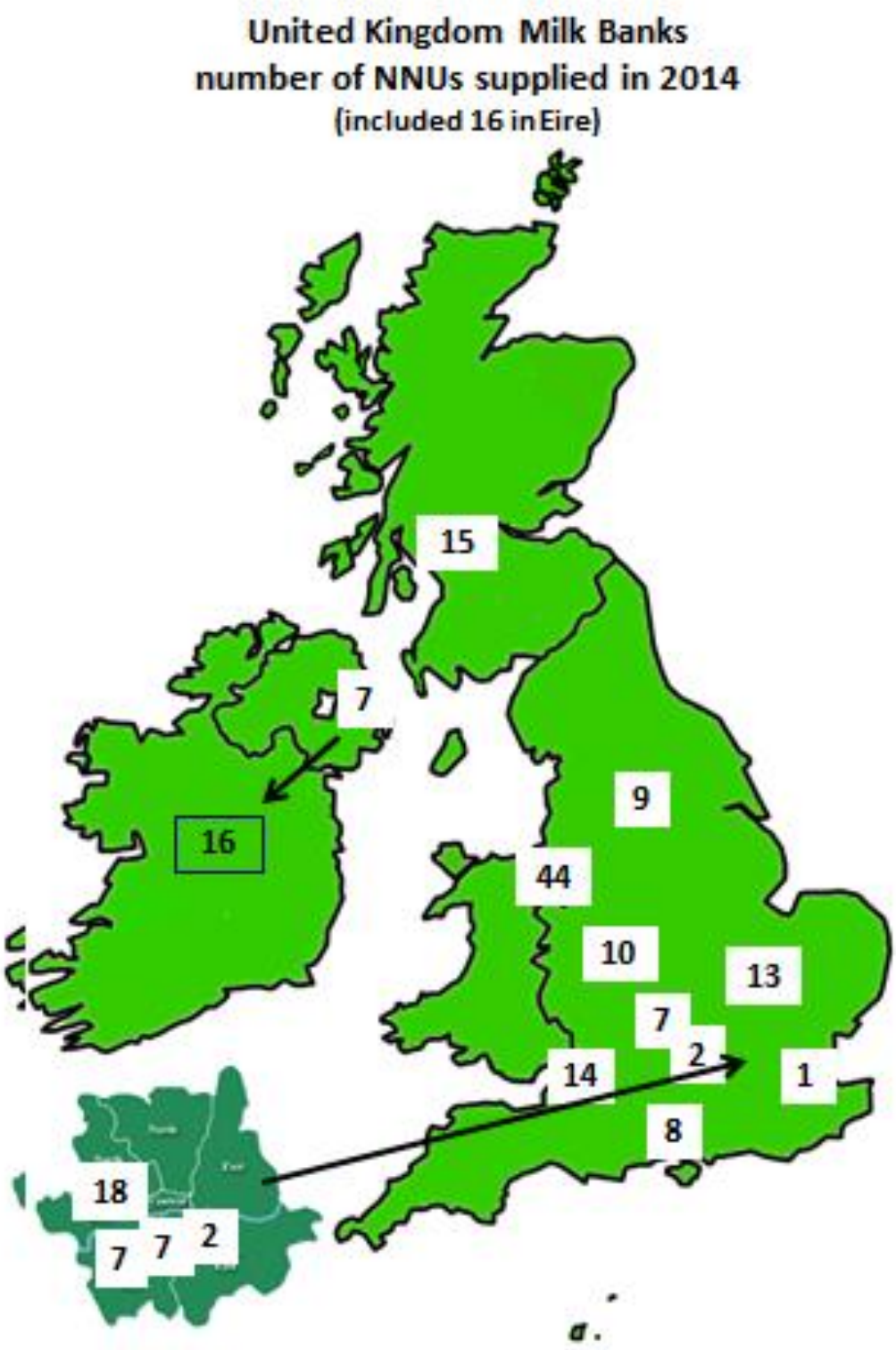





United Kingdom Donor Human Milk Bank Activity 2012 - 2014
Percentage of donated raw DHM unsuitable for use
80%
70%
60%
50%
40%
30%
20%
10%
0%
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
2014
2013
2012
Human Milk Banks


United Kingdom Donor Human Milk Bank Activity 2012 - 2014
Number of Neonatal Units supplied by each HMB
(includes 16 hospitals in Eire)
NOTE: An individual NNU may obtain DHM from more than one HMB
Number of NNUs
0
5
10
15
20
25
30
35
40
45
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
Human Milk Banks (HMB)
2014
2013
2012





Appendix 3. Resolution on the Use of Donor Human Milk for Muslim Infants

Resolution on the Use of Donor Human Milk for Muslim Infants

Draft statement (October 2015)

Background: The introduction of anonymised donor human milk (DHM) to countries with Muslim populations has been challenged by the Islamic concept of milk kinship. Here the sharing of milk, historically in the form of a wet nurse, creates kinship ties and thus marriage prohibitions between the family of the donor and the recipient. Surveys in the United Kingdom have shown that these beliefs may affect the acceptability of DHM to Muslim parents, and impact on the clinical use of DHM in Neonatal Units in areas with predominantly Muslim populations. Given the many benefits of DHM, especially in the prevention of necrotising enterocolitis in preterm infants, we believed it was necessary to find a resolution to this situation. In order to facilitate this, representatives from the Muslim Council of Britain (MCB), the United Kingdom Association for Milk Banking (UKAMB), and the British Association of Perinatal Medicine (BAPM) met at a Round Table Discussion on the 26th April 2015 in London.

Aims: To work together in an atmosphere of mutual respect and understanding to give vulnerable infants the best possible start in life, regardless of their religion or ethnicity.

Summary of Round Table Discussion: The National Institute for Health and Care Excellence (NICE) issued guidelines for the use of DHM throughout the United Kingdom in 2010. These state that every aliquot of DHM given must be traceable from donor to recipient.
Participants at the Round Table Discussion agreed that this means that, in the future, should there be doubt about whether a potential bride or groom had received DHM from a particular donor; it will be possible to address this.

The process would involve reviewing the recipient's medical records, in conjunction with records from the relevant Human Milk Bank, to rule out whether they had received milk from the same lactating mother. In the future, electronic barcode tracking is likely to be introduced. This will make the process more straightforward, and also extend the current 30 year limit for the retention of medical records as mandated by NICE.

Resolution: Concerns about milk kinship should not lead to donor human milk being with-held from vulnerable infants, as there are safeguards in place that guarantee the traceability of milk from donor to recipient.

Actions agreed upon:
1. To reinforce, via the inclusion of a statement in the soon to be published BAPM Framework for the use of DHM in the United Kingdom, the need for a robust system to ensure the traceability of donated milk. This would ideally be via an electronic bar code system.
2. To recommend at the next review of the NICE guidelines on the DHM that records for the use of DHM be kept for longer than the current standard of 30 years.
3. To produce a parent information leaflet explaining the rationale for the use of DHM, and steps that can be taken by families who are concerned about the implications of establishment of possible milk kinship.
4. To disseminate throughout the United Kingdom, via local religious communities and clinicians in neonatal units in areas with significant Muslim populations, this resolution.

Signatories:

Dr. Shuja Shafi, Secretary General of the Muslim Council of Britain
Mufti Zubair Butt, Islamic Medical Ethics Advisor to the Muslim Council of Britain
Dr. Syed Mohiuddin, Royal London Hospital
Dr. Morgan Clarke, University of Oxford
Gillian Weaver, UK Association for Milk Banking
Dr. Amanda Ogilvy-Stuart, British Association of Perinatal Medicine
Dr. Thomas Williams, British Association of Perinatal Medicine

Appendix 4. Clinical uncertainties and potential areas for future research

There are several areas where additional evidence is needed in order to improve and inform practice. The most important of these is the need for high quality trials in populations of infants relevant to UK practice that are adequately powered to determine benefits on short (e.g. NEC) and long-term (e.g. cognitive) outcomes. We have addressed some of the other issues already, but we have grouped below other areas that are important to consider

Organisational

- Which professional organisation(s) or governmental body should take the lead for national practice, guidelines and recommendations in the use of DHM?
- What is the optimal number of HMBs in the UK, and how might 'satellite' depots improve cost-effectiveness within networks?
- Where should HMBs be based locally i.e. within or separate from NNUs, and regionally i.e. location across the UK?
- How could transport mechanisms to (with donations) and from (DHM provision to NNU) be optimized and provided in a safe and sustainable manner.
- How should HMBs be funded and commissioned? Where HMBs provide DHM across more than one managed clinical network, how are costs best identified and apportioned?
- Is the current organisation set up and supply of DHM both safe and sustainable, and able to withstand changes in regional configurations of neonatal services?

Quality and technical issues

- Processing methodologies – how can these be improved or modified i.e. are there alternate methodologies that might better 'protect' both nutrient and non-nutrient factors e.g. functional proteins, and who should conduct and fund this work?
- Nutrient quality – what data should be made routinely available with individual batches of DHM, and how might clinicians best use this information in daily practice?
- Microbial cut-offs – what is the evidence base for current thresholds of bacterial counts in donated milk, and are there any productive uses for donated milk not meeting these thresholds?
- Are current QA and QC procedures sufficient to be sure that milk quality (drugs, contamination with bovine products, nicotine exposure etc.) is high?
- Is it necessary to confirm that the milk received was all provided by the mother using DNA matching techniques?

Clinical practice

- Which babies benefit from DHM e.g. near-term infants etc. and what level of equipoise exists for further controlled trials in specific sub-populations?
- What are the key question for future controlled trials i.e. comparison of DHM with artificial formula, use/timing of fortification, potential benefits (if any) of an exclusive human milk based diet etc.?
- How should NNUs address the question of DHM use in infants of mothers who choose not to provide OMM?

Safety and quality control

- Are current methods for tracking and tracing DHM exposure robust and/or how best can they be improved?
- Are there unresolved infective concerns e.g. viral, or other risks?

Health economic and cost-effectiveness

- What is the current level of evidence for efficacy and cost-effectiveness, and how can this be improved?
- What are the opportunity costs i.e. are there alternate strategies that might, for example decrease the incidence of NEC, that are more cost-effective than DHM?

Training and education for parents and staff?

- What current staff training packages are available for supporting use of OMM and DHM, and are they well balanced i.e. based on the best available evidence?
- What media and formats (leaflets, apps etc.) are best to support parents (for OMM and DHM), and how can they be improved?

Appendix 5. References

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Appendix 6. Electronic references and internet links of relevance to framework

UK NEC collaborative study details

http://www1.imperial.ac.uk/departmentofmedicine/divisions/infectiousdiseases/paediatrics/neonatalmedicine/ndau/research/nec_study/

UK milk banking leaflets

http://www.ukambukaHMB.org/info-for-hcps/leaflets/http://www.ukamb.org/info-for-hcps/leaflets/

Internet sites with parental information on DHM with link to UKAMB

Link to UKAMB
http://www.nhs.uk/conditions/pregnancy-and-baby/pages/breastfeeding-premature-baby.aspx#closeclose

Links plus a DVD for parents and professionals on using DEBM

http://www.chestermilkbank.orgorg.uk

Links plus a Medication and breast milk fact sheet

http://www.breastfeedingnetwork.orgorg.uk//

Donor milk banks: the operation of donor milk bank services http://www.nice.org.uk/guidance/CG93

Overview of donating with links to UKAMB
http://www.nct.org.uk/

Link to UKAMB
http://babyworld.co.uk/2011/06/how-to-donate-breast-milk/