

# GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF HUMAN MILK BANKS IN THE UK

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Human milk banks provide an alternative to formula feeds for preterm babies when the mother's breast milk is unavailable. The first human milk bank in the United Kingdom opened at Queen Charlotte's Hospital, London in 1939. The emergence of the human immunodeficiency virus resulted in the disappearance of many human milk banks in the 1980s. However, there are currently at least 16 operating in the UK, with others being developed. Most are attached to neonatal units (the one in Northern Ireland is based at a health centre and managed by a health visitor). The UK Association of Milk Banks, a registered charity, provides guidelines for their operation, and the third edition these guidelines were updated using a more rigorous evidence based methodology.

There are few studies specifically using pasteurised donor breast milk in preterm infants, and therefore much of the evidence has to be extrapolated from studies including babies fed at the breast and those fed their mother's own unpasteurised breast milk. The guidelines discuss what is known about the consequences of pasteurisation of breast milk for feeding to unrelated preterm infants. They cover the selection of donors, and the collection, preparation, storage and treatment of donor breast milk. They include information leaflets both for potential donors (with instructions) and mothers of recipient babies. There are good practice points on record keeping, staffing a milk bank, and archiving donor samples in case of a subsequent problem. They do not cover the management of mothers' milk fed to their own babies, nor the indications for using donor breast milk.

## MAIN POINTS (RECOMMENDATIONS GRADE D UNLESS STATED)

- ▶ When a mother's own milk is not available banked human milk confers clinically important benefits in outcome and should be provided for preterm infants, particularly those of very low birthweight [grade B]

### Lifestyle

- ▶ Donors should be non-smokers
- ▶ Donors should not consume more than 2 units of alcohol daily
- ▶ Donors should not exceed more than 3 caffeinated drinks (150–200 ml) daily [grade B]

### Medication

- ▶ Recommended daily levels of vitamin supplements are acceptable for donor mothers, but excessive doses of vitamins A, C, E and B6 should be avoided
- ▶ Donor mothers can continue taking the progesterone only contraceptive pill
- ▶ Mothers receiving thyroxine supplementation should have their T4 levels checked before donating milk
- ▶ Donor mothers can continue using salbutamol and steroid inhalers if they are asthmatic
- ▶ Topical antihistamine eye and nasal drops (sodium cromoglycate) can be used when donating milk
- ▶ Diabetic mothers receiving insulin can donate breast milk
- ▶ Donor mothers can continue taking iron supplementation
- ▶ Regular dosage of acetaminophen (paracetamol) should be avoided. Occasional dosage is acceptable
- ▶ If donors receive a course of antibiotics they should allow at least 24 hours after the last dose before expressing milk for the milk bank

### Infections

- ▶ Due to the risk of disease transmission via breast milk, donor mothers should agree to a blood test to be screened for:
  - HIV 1 and 2, HTLV I and II [grade B]
  - hepatitis B and C, syphilis
- ▶ Mothers should not donate milk to a milk bank for a month after rubella vaccination

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**Collection of milk**

- ▶ Breast pumps are a potential source of contamination and therefore require thorough cleaning and sterilisation
- ▶ Electric breast pumps should be used according to manufacturers' recommendations [grade C]
- ▶ Milk should not be collected and stored in polyethylene plastic bags
- ▶ Stainless steel containers are not suitable for the collection of donor milk [grade C]
- ▶ Non-sterile bottles are acceptable for the collection of milk if they are clean and dry [grade C]
- ▶ Drip breast milk is not suitable for collection as donor milk because of the low calorie content but it is recognised that it has benefits in other situations

**Storage of milk**

- ▶ Donor milk should be refrigerated immediately [grade C]
- ▶ Donor milk can be stored at 4°C in a refrigerator for up to 24 hours [grade C]
- ▶ Donor milk should not be stored in the ice making compartment of a domestic refrigerator for more than one week but should be transferred to a freezer at -20°C as soon as possible [grade C]
- ▶ Donor milk should be frozen as soon as possible to prevent lipid peroxidation, remove viable CMV (cytomegalovirus), and preserve vitamin C content [all grade C]
- ▶ Raw donor milk can be stored frozen at -20°C for up to three months without loss of essential enzymes (except for lactoperoxidase) and lipids [grade C]
- ▶ Raw donor milk should not be stored frozen for longer than three months because of lipolytic activity and loss of vitamins [grade C]
- ▶ Raw donor milk should not be refrozen after thawing [grade C]
- ▶ Thawed milk should not be left at room temperature for longer than 2 hours before pasteurisation [grade C]

**Bacteriological testing of milk**

- ▶ All bottles of donor milk should be tested for counts of bacteria [grade C]
- ▶ CLED or Columbia agar are suitable media for testing for bacteria [grade C]
- ▶ 24 hour incubation of agar plates is sufficient [grade C]

**Heat treatment of donor breast milk**

- ▶ Pasteurisation for 30 minutes at 62.5°C removes CMV, inactivates HIV, inactivates HTLV, and kills bacteria [all grade C]
- ▶ Milk should be thawed before heat treatment to ensure adequate heat treatment [grade C]
- ▶ Bottles should not be submerged during the cooling cycle

**Handling of breast milk**

- ▶ Repeated freezing and thawing is not recommended because of increased hydrolysis of lipids [grade C]
- ▶ Thawed breast milk should be handled aseptically [grade C]
- ▶ Milk does not need to be shielded from phototherapy lights when tube feeds are being administered [grade C]
- ▶ Milk should not be thawed and heated in a microwave oven [grade C]

**Archiving samples of breast milk**

- ▶ Samples can be stored at -70°C [grade C]

**COMMENTARY**

The guidelines provide comprehensive advice to those operating human milk banks, supported by a detailed review

**Recommendation grades and levels of evidence**

Grade	Evidence
A	At least one high quality meta-analysis, systematic review of RCTs or RCT with a very low risk of bias and directly applicable to the target population, or a body of evidence principally from well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias, directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence from high quality systematic reviews of case-control or cohort studies or high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relation is causal, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from high quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
C	A body of evidence from well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relation is causal, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from high quality systematic reviews of case-control or cohort studies or high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
D	Evidence from non-analytic studies, eg, case reports, case series; evidence from expert opinion; or extrapolated evidence from case control or cohort studies with more than a very low risk of confounding, bias, or chance, and less than a high probability that the relation is causal

of the evidence based on a thorough literature search. The recommendations should be used for quality assurance of the operation of milk banks.

Those contemplating setting up a milk bank will find a fully referenced review of the benefits of feeding pasteurised donor milk to preterm infants. The guidelines demonstrate the paucity of direct research evidence about the use of pasteurised donor milk in preterm infants. A number of studies have demonstrated short and long term benefits from the use of breast milk over preterm formula feeds. The references cited provide direct evidence of benefit in preterm infants from pasteurised donor milk for the prevention of necrotising enterocolitis and its association with lower blood pressure in adolescence. These are the parts of the statement about the benefits for which a grade B is appropriate.

Another major consideration is the risk of transmitting serious infections, especially HIV. Whereas there is no direct evidence of risk of transmission of HIV from pasteurised breast milk, the guidelines are necessarily based on the assumption of risk, and include criteria for excluding potential donors, and a requirement for potential donors to be serologically tested.

The guidelines list 16 neonatal units in the UK that consider the use of pasteurised donor milk to be sufficiently beneficial to justify maintaining a milk bank. Other units considering setting up their own milk banks will find the guidelines valuable in weighing up the evidence of benefit against the costs and potential infection risks.

The guidelines are available via [www.ukamb.org](http://www.ukamb.org) (priced at £20)