NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Donor breast milk banks: the operation of donor breast milk bank services

1.1 Short title

Donor breast milk banks

2 Background

a) The Department of Health has asked the National Institute for Health and Clinical Excellence (NICE or 'the Institute') to develop a guideline on the use of donor breast milk in preterm babies for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (see appendix B). The guideline will provide recommendations for good practice on the operation of donor breast milk banks that are based on the best available evidence.

b) NICE clinical guidelines support the implementation of National Service Frameworks (NSFs) in those aspects of care for which a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by NICE after an NSF has been issued have the effect of updating the Framework.

c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment. NICE also produces

service guidance, which focuses on the broad configuration and provision of clinical services rather than on details of clinical practice. It should be noted that this guideline will be structured as service guidance on the operation of donor breast milk banks.

3 Clinical need for the guideline

a) Research has consistently shown that breast milk is the best nourishment for babies and that it has important benefits to an infant's health in the short, medium and long term. Women are recommended to breastfeed their baby exclusively for 6 months and continue to breastfeed after 6 months as part of a balanced diet, for as long as mother and baby wish.

b) If a mother does not wish to express milk despite discussion with experienced staff and information regarding benefits to herself and her baby, or is not able to express sufficient milk, donor breast milk can be used as an alternative to infant formula, because it has been shown to have significant nutrient and non-nutrient benefits.

c) A Health Technology Assessment (HTA) report entitled 'Breastfeeding promotion in special care and neonatal intensive care units; an evidence synthesis' is due to be published in July 2009. This report uses systematic review methodology to assess which interventions effectively promote the initiation and duration of breastfeeding in neonatal, special, and intensive care settings, including the availability of donor breast milk. This guideline will refer to the HTA report as appropriate where evidence on the role of donor breast milk in breastfeeding initiation and continuation is needed.

d) Concerns have been raised on the safety of handling and processing donor breast milk (for example, adequate pasteurisation) and on the long-term safety of donor milk, in particular regarding the transmission of prion diseases such as Creutzfeld–Jakob disease.

e) Currently, 17 donor breast milk banks are in operation in the UK; these provide donor milk to babies, including preterm babies and babies with growth restriction. The key guideline is the 2003 UK Association for Milk Banking 'Guidelines for the establishment and operation of human milk banks in the UK'; however, this is past its review date for updating, but still relevant and in use. There is therefore an urgent need for an updated national guideline to ensure that donor milk banks operate according to best available evidence and standards of practice. Local needs will determine how services are commissioned to implement the guideline recommendations.

4 The guideline

a) The guideline development process is described in detail in two publications that are available from the NICE website (see section 6, 'Further information').

b) This scope defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on a referral from the Department of Health (see appendix A).

c) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Infants who receive donor breast milk.

b) Mothers and carers of infants who receive donor breast milk.

c) Women who donate breast milk.

d) Staff involved in the collection, storage and handling of donor milk.

4.1.2 Groups that will not be covered

a) Infants who do not receive donor breast milk.

b) Mothers and carers of infants who do not receive donor breast milk.

4.2 Healthcare setting and services

a) Donor breast milk banks.

b) Special care baby units, neonatal units, transitional care units and other settings (such as paediatric wards) that require access to donor breast milk.

c) Community services that support breast milk donors and mothers or carers of infants receiving donor milk.

4.3 Clinical management

The following areas of clinical management have direct implications for service delivery.

4.3.1 Areas that will be covered

a) Recruitment, assessment and selection of donor women. This will include:

- an assessment of factors that affect suitability, including:
  - relevant lifestyle factors, such as smoking status and alcohol intake
  - relevant medical history, including existing conditions or infections, vaccination history and current medication
- serological testing of potential donors.

Reasons for stopping donation of breast milk, either temporarily or permanently, will also be covered.

b) Collection, storage and handling of donor breast milk. This will include:

- collection of donor milk
- storage of milk at the donor's home, during transportation and at the milk bank, including refrigeration and freezing
- testing and treatment of donor milk, including pasteurisation
- pooling of donor milk
- archiving of donor milk samples
- disposal of donor milk samples.

c) Administration of the collection, storage and handling of donor breast milk, specifically the tracking and tracing of milk. This will also include the administration of records of consent to donation and to use of donor milk.

d) Training and competencies of donor breast milk bank staff.

e) Training and competencies of other staff working with mothers and babies who may benefit from, or who are receiving, donor milk, and those working with donors and potential donors.

f) Information for parents or carers, donors and potential donors. The needs of different ethnic, religious and cultural groups will be considered.

4.3.2 Areas that will not be covered

a) Indications for use of donor breast milk.

b) Collection, storage and handling of breast milk for a mother's own baby.

4.4 Key outcome measures

a) Safety of donor milk, defined as the minimisation of transmission risk for specific conditions, such as Creutzfeld–Jakob disease.

b) Process measures of service delivery. For example, rates of screened donor women who are accepted as donors, and the number of milk donations with complete tracking and tracing data.

4.5 Economic aspects

The developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. They will conduct a review of the economic evidence and carry out analyses as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

It should be noted that because this guideline focuses on identifying the optimal configuration of a milk bank service and not the indications for donor breast milk per se, a cost-effectiveness analysis of the health benefits of donor milk will not be undertaken. Moreover, it is not clear that QALYs can be estimated appropriately for this guideline. Any departures from preferred NICE methods will be clearly documented. It is anticipated that the key outcome of any analysis would relate to the avoidance of any significant safety risks (see section 4.4).

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Guideline

The development of the guideline recommendations will begin in April 2009.

5 Related NICE guidance

Published

Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households. NICE public health guidance 11 (2008). Available from www.nice.org.uk/PH11

Routine postnatal care of women and their babies. NICE clinical guideline 37 (2006). Available from www.nice.org.uk/CG37

6 Further information

The guideline development process is described in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/guidelinesmanual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).

Appendix A: Referral from the Department of Health

The Department of Health asked NICE:

'To produce a short clinical guideline on the use of human donor breast milk in preterm babies.'