National Institute for Health and Clinical Excellence

Donor milk banks: the operation of donor milk bank services

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NICE clinical guideline 93

www.nice.org.uk/cg93

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Introduction

Research has consistently shown that breast milk is the best nourishment for babies and that it is highly beneficial to their 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 (see the latest Department of Health guidance on breastfeeding).

If, after discussion with experienced staff, a mother is unable to express sufficient milk or does not wish to express milk for a baby unable to feed at the breast, donor breast milk can be used.

In this guideline, donor breast milk is defined as breast milk expressed by a mother that is then processed by a donor milk bank for use by a recipient that is not the mother's own baby. Payment for the donated milk is not given.

A Health Technology Assessment (HTA) report entitled 'Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis' was published in 2009. This report used systematic review methodology and health economic modelling to assess which interventions, including the availability of donor breast milk, effectively promote the initiation and duration of breastfeeding in neonatal, special and intensive care settings. The authors noted that in the UK, donor breast milk is neither widely nor readily available in the majority of units; this was reflected through modelling the use of donor breast milk by availability, not need. They concluded that if mechanisms by which donor milk is provided were improved, donor milk would become cost effective compared with using formula. This was based on a significant improvement in the operation of milk banking, and suggested models include setting up a national donor milk banking system similar to that for blood (Renfrew et al. 2009).

Although this guideline does not make recommendations on the configuration of services, it does make recommendations on the safe and effective operation of donor milk services.

Throughout development, the safety of donor breast milk was considered to be the aim of the guideline and recommendations were made to minimise the risk to recipients of donor milk. Maximising safety comes at a cost and recommendations were made to observe the best possible safety standards without exceeding opportunity costs acceptable to society.

Patient-centred care

This guideline offers best practice advice on the operation of donor breast milk bank services.

Good communication between healthcare professionals and women is essential. It should be supported by evidence-based written information tailored to the women's needs. The information women are given should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Key priorities for implementation

Quality assurance

- Use Hazard Analysis and Critical Control Point (HACCP) principles in all quality assurance processes.
- Validate, calibrate and maintain all equipment used in donor milk handling and processing and keep records of this. Ensure that the equipment is used according to the manufacturer's instructions.
- All milk bank staff should have ongoing training that is relevant to their job and is recorded. Training should cover good practice and should ensure that each staff member:
  - is competent in performing their job
  - understands the technical processes relevant to their job
  - understands how the milk bank is organised and how its health and safety and quality systems work
  - understands the regulatory, legal and ethical aspects of their work.
- All donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks.

Screening and selecting donors

- Follow the stepped screening process detailed in recommendations 1.12 to 1.21 when recruiting donors.
- Do not routinely repeat serological tests while the donor is donating milk.

Handling donor milk at the milk bank

- Before pasteurisation, test a sample from each batch of pooled donor milk for microbial contamination and discard if samples exceed a count of:
  - 10^5 colony-forming units (CFU)/ml for total viable microorganisms **or**
  - 10^4 CFU/ml for Enterobacteriaceae **or**
  - 10^4 CFU/ml for Staphylococcus aureus.
- Regularly test pasteurised donor milk for microbial contamination. Base the testing schedule on the volume and throughput of milk. Test:
  - either at least once a month or every 10 cycles, depending on which comes first

    and
  - on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.

Tracking and tracing

- At all stages, donor milk containers should be labelled clearly for identification. Clearly identify milk that is ready to be used.
- Only supply donor milk to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.

1 Guidance

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

The recommendations in this guideline are all key to the process of donor milk banking and are dependent on each other. For example, the recommendations on testing milk post-pasteurisation are dependent on the application of the recommendations on quality assurance and equipment maintenance. The safety of donor milk therefore depends on the implementation of all recommendations.

Quality assurance

There is no recognised NHS standard for human milk pasteurisers. In the UK, donor milk banks have been following guidance issued by various bodies, including in 1981, a report on the collection and storage of human milk. (Committee on Medical Aspects of Food Policy 1981) and more recently, guidelines issued in 2006 by the UK Association for Milk Banking. The following recommendations, specifically on maintenance of equipment, need to be viewed in this context.

1.1 Use Hazard Analysis and Critical Control Point (HACCP) principles in all quality assurance processes.

1.2 Clean and store all donor milk containers and equipment according to local protocols based on HACCP principles.

1.3 Validate, calibrate and maintain all equipment used in donor milk handling and processing and keep records of this. Ensure that the equipment is used according to the manufacturer's instructions.

1.4 Regularly inspect all equipment used in donor milk handling and processing, following the manufacturer's instructions. Ensure that all equipment that may affect temperature or contamination levels has sensors and alarms so that constant conditions can be maintained.

1.5 All milk bank staff should have ongoing training that is relevant to their job and is recorded. Training should cover good practice and should ensure that each staff member:

- is competent in performing their job
- understands the technical processes relevant to their job
- understands how the milk bank is organised and how its health and safety and quality systems work
- understands the regulatory, legal and ethical aspects of their work.

1.6 Train milk bank staff in HACCP principles, food hygiene and pasteurisation, and provide ongoing support so that practices reflect these principles.

1.7 All donor milk administered in the NHS should be from milk banks that can demonstrate adherence to the NICE guidance on the operation of donor milk banks.

1.8 Implement a quality control system that is followed by all staff and is reviewed regularly. It should encompass:

- collecting, testing, processing, storing and transporting milk
- personnel, required documentation, premises and equipment
- batch recall, external and internal auditing, non-conformance to processes and self-inspection
- continuous quality improvement.

Recruiting donors

1.9 When promoting the donation of breast milk, aim to reach as many potential donors as possible through a variety of channels, including:

- providing written information to be left in:
  - GP surgeries
  - antenatal clinics and postnatal wards
  - volunteer and other organisations working in maternity and childbirth
  - children's or Sure Start centres
  - maternity shops
- direct referrals or recommendations by:
  - current and previous donors
  - staff at neonatal intensive care units
  - paediatricians assessing babies' progress
  - health visitors (or other healthcare professionals providing postpartum care)
  - childbirth educators
  - organisers and attendees of prenatal and postnatal classes
  - breastfeeding mothers' support groups and related organisations
- features in the media.

1.10 Use clear, non-technical language when communicating the use of donor milk and the process of donor milk banking in any written information and activities.

Screening and selecting donors

The following strategy of screening and selection is part of the whole process of donor milk handling and therefore is intrinsically linked with the recommendations on testing and treating the donor breast milk.

1.11 Follow the stepped screening process detailed in recommendations 1.12 to 1.21 when recruiting donors.

1.12 Advise a potential donor that she is not eligible to donate milk if she:

- currently smokes or uses nicotine replacement therapy (NRT)
- regularly exceeds recommended alcohol levels for breastfeeding mothers (1 to 2 units, once or twice a week) (see Department of Health website for information on alcohol and breastfeeding)
- is using, or has recently used, recreational drugs
- has previously tested positive for HIV 1 or 2, hepatitis B or C, human T-lymphotropic virus (HTLV) type I or II, or syphilis
- is at an increased risk of Creutzfeldt–Jakob disease (CJD) (see HPA website for information on the risk of CJD).

  Include this information in recruitment material so that potential donors can self-screen for these criteria.

1.13 Using a process of informal interview, referring to medical sources (with consent) if necessary, ask the potential donor questions on the topics that follow. Use the information she gives to make a balanced decision about her eligibility to donate based on possible risks to recipients and/or the results of subsequent serological tests (see recommendations 1.16 and 1.17). Ask questions about:

- her health: to confirm that she is in good general health
- her baby: document the age and health of the baby
- any exposure to passive smoke: is she exposed to high or sustained levels of passive smoke (for example, do other members of her household smoke heavily)?
- any medication that she is taking: is she currently taking any medication or undergoing any other medical therapy?
- any significant environmental or chemical exposure (such as contamination of the local water supply): is she exposed to high or sustained levels of environmental or chemical contaminants that can be expressed in breast milk?

- any recent exposure to infection (including HIV 1 or 2, hepatitis B or C, HTLV I or II, syphilis, herpes, or acute or chronic infections). Depending on the assessment of level of risk, further testing may be needed.
- any recent medical intervention (for example, exposure to diagnostic radioactive isotopes)
  - refer to guidance from the Department of Health on the safety of recent vaccination when breastfeeding.

    Advise the potential donor that depending on her answer to any of these questions she may not be eligible to donate milk.

1.14 If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions (recommendations 1.12 to 1.13) for the period when the milk was expressed.

1.15 Conduct the screening interview, detailed in recommendations 1.12 and 1.13, with potential donors at a mutually acceptable time and place, either face-to-face or by telephone.

Serological testing

1.16 When donors first contact the milk bank about donating milk, explain that serological testing is mandatory to reduce the risk of passing on infections. Obtain informed consent before testing.

1.17 Undertake serological testing of all potential donors for the following and exclude women from donating who test positive for:

- HIV 1 or 2
- hepatitis B or C
- HTLV I or II
- syphilis.

1.18 Perform all serological screening tests at the time of enrolling for donor milk banking; do not rely on antenatal test results.

1.19 All tests should be undertaken in laboratories with clinical pathology accreditation (CPA).

1.20 Ensure that laboratories communicate the results of serological testing clearly and that they provide appropriate interpretive comments.

1.21 Give serological test results to potential donors either in person or by telephone (unless they prefer to receive them in writing). If needed, offer further help and support based on local protocols, including information about counselling and local support groups.

1.22 Laboratories should archive samples of blood received from donors.

Consent and continued eligibility

1.23 Before accepting a donor's milk, obtain her consent for the processing and intended use of the donated milk. Advise her that once donated, milk will not be returned to her.

1.24 While a donor continues to donate, ask regularly about her general health and the exclusion criteria detailed in recommendations 1.12 to 1.13. Advise her that if her status or circumstances change in relation to these, she should contact the milk bank immediately.

1.25 Do not routinely repeat serological tests while the donor is donating milk.

Training and supporting donors

The recommendations in this section are specific to mothers expressing milk for donation, and may differ from advice given to mothers expressing milk for their own babies.

1.26 Provide all new donors with training, preferably face-to-face with additional information by telephone and in writing. Arrange training at a time and place suitable for both donor and trainer.

1.27 Training for new donors should cover:

- hand washing and the importance of this
- good personal hygiene
- collecting and expressing milk, including cleaning and using breast pumps and containers
- storing donated milk (including cooling and freezing)
- labelling donated milk, and documenting storage conditions
- transportation of donated milk (if needed).

1.28 Provide ongoing support to all donors according to their individual needs until no longer required. This may include:

- information and ongoing support on milk bank requirements for their diet and alcohol consumption
- continued support for collecting expressed milk and maintaining lactation
- emotional support.

1.29 Offer additional support and information on milk collection to donors whose milk has significant or repeated microbial contamination.

Stopping or suspending milk donations

The recommendations in this section are specific to mothers expressing milk for donation, and may differ from advice given to mothers expressing milk for their own babies.

1.30 Consider no longer accepting breast milk from donors who, despite support, consistently supply:

- breast milk that does not meet the microbiological criteria (see recommendation 1.58)
- small amounts of breast milk.

1.31 Advise donors to contact the milk bank to discuss suspending or stopping their breast milk donation if they develop a fever or have contact with a viral exanthematous disease.

1.32 Advise donors who begin taking any medication that they should contact the milk bank to discuss suspending or stopping their breast milk donation. Use appropriate reference sources[1].

1.33 Advise donors to contact the milk bank to discuss suspending or stopping their breast milk donation if they develop lesions or infections of the breast (including mastitis or herpes).

1.34 Provide donors who are stopping their breast milk donations with as much advice and support as needed.

1.35 Consider the size of the recipient population, the milk bank's stock levels, and the preferences of the donor when discussing how long a woman can donate milk.

Expressing milk at home for donation

1.36 Advise donors to collect expressed milk rather than 'drip' milk (milk that is passively collected from one breast while the baby feeds at the other) for donation.

1.37 Actively encourage donors to hand express milk; however, accept pump-expressed milk if donors prefer this method.

Handling donor milk at home

The recommendations in this section are specific to mothers handling and storing milk for donation, and may differ from advice given to mothers expressing milk for their own babies. This

is because donated milk needs to undergo various testing and treatment processes at the donor milk bank, all of which affect the nutritional and immunological composition of the milk. The aim therefore is to make sure that milk for donation reaches the donor milk bank as soon as possible to ensure the highest quality before processing.

1.38 Advise donors that expressed milk collected for donation should be frozen as soon as possible to maintain the nutritional and microbiological quality of the milk. If this is not possible (for example, because of storage capacity), advise donors to refrigerate samples collected over 24 hours, and then freeze the batch.

1.39 Advise donors that expressed milk for donation should remain frozen during storage at home, and if they have any concerns about storage conditions or freezer temperatures, they should discuss these with the milk bank.

1.40 Advise donors that frozen expressed milk should be transported to the milk bank as soon as possible. However, if necessary, expressed milk for donation can be stored before transport to the milk bank for up to 3 months in a domestic freezer, at −18°C or lower. If a donor does not have access to a domestic freezer at her home, she may be able to access freezers for milk storage at local donor milk depots or children's centres.

1.41 Advise donors that expressed milk can only be accepted by the milk bank if it has been collected and stored in milk collection containers provided by, or acceptable to, the milk bank.

1.42 Advise donors that collection containers for expressed milk should be used according to instructions provided by the milk bank.

1.43 Ensure that donors can check and document their freezer temperature every day; this may include providing a thermometer.

Handling donor milk during transportation

1.44 Define critical conditions for transport, including temperature and time limit, to ensure that donor milk remains frozen during transport.

1.45 Transport donor milk in secure, tamper-evident containers and packaging.

1.46 If donor milk is transported to the milk bank by a contracted third party, ensure that a documented agreement is in place to maintain the conditions needed.

1.47 Define in writing the milk bank's procedures for transporting and storing donor milk. Ensure that these procedures maintain the quality of the donor milk and allow accurate identification of samples. Keep records of inventory and distribution (see also recommendations 1.68 to 1.75 on tracking and tracing).

1.48 Collect expressed milk from the donors, preferably using an agreed transport provider (ideally a medical courier) or a member of staff from the milk bank. In some instances, donors may be required or may wish to deliver their own milk to the milk bank or depot, in which case they should also follow the milk bank's requirements for transport as outlined. In all cases, use consistent monitoring processes, including recording the journey time.

1.49 Collect expressed milk from either the donor's home (see recommendations 1.38 to 1.43) or from donor milk depots that have practices for monitoring freezers and maintaining standards for quality control, storage and security. Ensure that similar processes are in place in any location where the donor milk is stored.

Handling donor milk at the milk bank

The following strategy of handling milk at the milk bank, specifically testing and treating donor milk, is part of the whole process of donor milk handling and therefore is intrinsically linked with the recommendations on recruiting and selecting the donors. It is also predicated on the effective functioning of the human milk pasteuriser.

1.50 Process all donated milk under hygienic conditions (a sterile environment is not necessary). Practise good hand hygiene at all times, and wear gloves whenever handling donor milk.

1.51 Check that donated milk arriving at the milk bank:

- is labelled correctly with the donor's name and the date of expression **and**
- has remained frozen **and**
- has not been tampered with.

Transfer all donated milk immediately to the freezer.

1.52 Store pasteurised and unpasteurised donor milk in separate freezers and refrigerators.

1.53 Store donor milk awaiting pasteurisation in the freezer at the milk bank (at −20°C) for no longer than 3 months from the date of expression.

1.54 Discard breast milk from donors who do not meet the selection criteria detailed in recommendations 1.12, 1.13 and 1.17.

1.55 Before testing and pasteurising, thoroughly thaw the donor milk, and keep in the refrigerator for no longer than 24 hours. Prevent the donor milk from reaching 8°C while thawing.

1.56 Only pool pre-pasteurised breast milk from the same donor.

1.57 Do not pool:

- breast milk from different donors,

or

- batches of pasteurised breast milk from the same donor.

1.58 Before pasteurisation, test a sample from each batch of pooled donor milk for microbial contamination and discard if samples exceed a count of:

- 10^5 colony-forming units (CFU)/ml for total viable microorganisms **or**
- 10^4 CFU/ml for Enterobacteriaceae **or**
- 10^4 CFU/ml for Staphylococcus aureus.

1.59 Ensure that laboratories communicate the results of microbial testing clearly and that they provide appropriate interpretive comments.

1.60 Seek help from microbiological laboratories to identify and investigate instances of significant or unusual contamination (for example, by undertaking further microbial tests).

1.61 Pasteurise donated milk at 62.5°C for 30 minutes in a human milk pasteuriser. Rapidly cool the milk to a temperature of 4°C or lower. Remove one bottle for testing if appropriate, then move the remainder of the batch to the freezer.

1.62 After pasteurising, store frozen donor milk for no longer than 6 months after the date of expression.

1.63 Do not open the lid of batches of pasteurised donor milk until the milk is to be used, unless it is to test the milk. If the milk is tested, discard the opened bottle.

1.64 Regularly test pasteurised donor milk for microbial contamination. Base the testing schedule on the volume and throughput of milk. Test:

- either at least once a month or every 10 cycles, depending on which comes first,

  and

- on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.

1.65 Discard pasteurised donor milk that has a total viable microbial count of 10 CFU/ml or more.

1.66 Keep all donor milk in containers made of food grade materials.

1.67 Staff at the milk bank should not be responsible for adding anything to the donated milk.

Tracking and tracing

1.68 Track donated milk from the donor through to the recipient hospital.

1.69 Tracking and monitoring of donor milk processing should include freezer temperatures, pasteurisation processes and stock control.

1.70 At all stages, donor milk containers should be labelled clearly for identification. Clearly identify milk that is ready to be used.

1.71 For each donor milk batch, keep the following records.

- About the donor:
  - NHS number/donor ID
  - consent
  - relevant medical history
  - results of serological tests.
- About each container before pasteurisation:
  - donor ID
  - a testing log, including the tests undertaken and their results.
- For each pasteurised container:
  - samples making up the batch
  - the batch number
  - a testing log, including the tests undertaken and their results
  - pasteurisation details, including date of the pasteurisation.
- The hospital or neonatal unit that receives the donated milk, or the disposal date of the donated milk, as appropriate.

1.72 Label each container of pasteurised donor milk with the following information.

- A unique identification number.
- Confirmation that it contains pasteurised donor breast milk.
- Instructions to keep frozen, and use within 24 hours if defrosted.
- An expiry date (no later than 6 months from expression).

1.73 Only supply donor milk to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.

1.74 The receiving hospital or neonatal unit should keep a record of how the donor milk is used. It should document for each bottle of donor milk:

- the baby's name, NHS number and date of birth, and the date administered
- the batch number and the date the donor milk was used in the patient record of each baby
- the condition of the donor milk on arrival following transport
- the storage conditions.

Ensure that all records (including raw data) that are critical to the safety and quality of the donor milk are kept for at least 30 years after expiry date, use or disposal. These records should be confidential.

[1] See the British national formulary for children, the Drugs and Lactation Database LactMed or the UK Drugs in Lactation Advisory Service

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from our website – click on 'How this guidance was developed'.

3 Implementation

NICE has developed tools to help organisations implement this guidance.

4 Research recommendations

We have made the following recommendations for research, based on our review of evidence, to improve NICE guidance in the future.

Although it was not part of the scope of this guideline, it is known that there is limited high-quality evidence on the benefits of donor breast milk. The aim of this guideline is to provide guidance on the operation of donor milk banks; however, our expectation is that, once any risks of donor milk banking are minimised, further research can be undertaken to evaluate the benefits of donor milk, and to identify the recipient babies who would benefit most.

The research recommendations below relate to the process of donor milk banking. Where appropriate, they also recommend evaluating outcomes in the recipient population.

4.1 The process of handling donor milk

What is the effect of the process of milk banking on the nutritional and immunological components of donor milk?

Why this is important

The handling of donor milk includes a range of processes – including transport, storage and heat treatment – and is known to affect various biological, nutritional and immunological properties of breast milk. In addition, new methods of processing, such as heat or pressure treatment, are now being used in the food industry. However, there is very little comparative evidence on the different effects of the processes and how changes in the detailed process (for example, a change in temperature of 1°C) may affect the biological, nutritional and immunological properties of the milk. There is also no direct evidence of how these changes affect outcomes for recipients.

Further research is needed on the comparative effects of all milk handling processes on nutritional and immunological components, and, where possible, the impact of these on health outcomes for the recipients and on resource use during milk banking and following supply to recipients.

4.2 Nutritional assessment of donor milk

How and when should the nutritional components of donor breast milk be assessed?

Why this is important

It is known that the process of donor milk banking (for example, storage and heat treatment) affects the nutritional composition of milk. It is not clear how such changes affect health outcomes for recipients. Currently, in the UK, nutritional assessment of donor breast milk is not common practice.

Further research is needed to define clinically important changes and to determine the most useful methods and timing of measuring these in UK milk banking practice.

4.3 Milk donors

What are the attitudes and behaviours (including lifestyle factors such as diet) of milk donors, and can they affect the quality of donor milk?

Why this is important

There is very limited evidence on the attitudes and behaviours of milk donors, including the reason why they choose to donate. There is no evidence on how these factors (for example, ongoing donation or a one-off donation or dietary behaviours) may be associated with the quality of donated milk.

Further research is needed to understand the link between donor attitudes or behaviours and the quality of milk.

5 Other versions of this guideline

5.1 Full guideline

The full guideline,' Donor breast milk banks: the operation of donor milk bank services', contains details of the methods and evidence used to develop the guideline.

5.2 Quick reference guide

A quick reference guide for healthcare professionals is available.

5.3 'Understanding NICE guidance'

A summary for patients and carers ('Understanding NICE guidance') is available.

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about milk donation.

6 Related NICE guidance

Published

- Maternal and child nutrition. NICE public health guidance 11 (2008).
- Postnatal care. NICE clinical guideline 37 (2006).

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group and the Short Clinical Guidelines Technical Team

Guideline Development Group

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Short Clinical Guidelines Technical Team

A short clinical guidelines technical team was responsible for this guideline throughout its development. It prepared information for the Guideline Development Group, drafted the guideline and responded to consultation comments. The following NICE employees made up the technical team for this guideline.

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Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

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About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

The guideline was developed by the Short Clinical Guideline Technical Team. The team worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual. This guideline was developed using the short clinical guideline process.

We have produced a summary for patients and carers. Tools to help you put the guideline into practice and information about the evidence it is based on are also available.

Changes since publication

20 December 2011: Copied into NICE guideline template, links checked.

Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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