

PRESS RELEASE

NICE's January interventional procedures guidance includes guidance on off-pump coronary artery bypass, extracorporeal membrane oxygenation in postneonatal children and transilluminated powered phlebectomy for varicose veins

The National Institute for Clinical Excellence (NICE) is today launching five pieces of guidance from its interventional procedures programme, covering new surgical procedures used in a variety of clinical areas. In the guidance issued today, NICE finds that:

- Current evidence on the safety and efficacy of **off-pump coronary artery bypass (OPCAB)** appears adequate to **support the use** of this procedure, provided that normal arrangements are in place for consent, audit and clinical governance. This recommendation applies to the procedure only when performed through a median sternotomy.
- Current evidence on the safety and efficacy of the **extracorporeal membrane oxygenation in postneonatal children** appears adequate to **support the use** of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance. All children undergoing this treatment, including those treated after cardiopulmonary bypass, should be entered onto the international registry of the Extracorporeal Life Support Organization (ELSO), based at the University of Michigan, USA (www.elseo.med.umich.edu).
- Current evidence on the safety and efficacy of **radiofrequency volumetric tissue reduction for turbinate hypertrophy, transilluminated powered phlebectomy for varicose veins**, and **extracorporeal oxygenation (ECMO) in adults** does **not** appear adequate to support the use of these three procedures without special arrangements for

consent and for audit or research. Clinicians wishing to undertake any of these procedures should inform the clinical governance leads in their Trusts. They should ensure that patients offered these procedures understand the uncertainty about the procedures' safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation of these three procedures at present. ECMO in adults is under evaluation in the Health Technology Assessment Programme's CESAR (Conventional Ventilation or Extracorporeal Membrane Oxygenation for Severe Adult Respiratory Failure) trial. Clinicians wishing to undertake this procedure are strongly advised to enter eligible patients into this trial.

Andrew Dillon, NICE Chief Executive said: "The interventional procedures programme focuses on new procedures and considers whether they are safe enough and work well enough for use in NHS. Today's guidance covers five procedures: two procedures where we have been advised that the data appears adequate to support their use; and three procedures where we have been advised there is uncertainty. Where such uncertainty exists we advise the NHS that patients should be kept fully informed and that clinicians should monitor and audit the results of procedures they undertake carefully. This means that the procedures could be used in the NHS, provided that it is in a carefully controlled way".

He added "Each piece of guidance is supported by *Information for the Public*, including patients and their carers, which will assist them in understanding the guidance we have issued to the NHS".

Ends

For more information call Sarita Tamber or Fraser Woodward on 020 7067 5900 and 07879 846787.

Notes to Editors

1. The full guidance on off-pump coronary artery bypass (OPCAB) can be found at <http://www.nice.org.uk/IPG035guidance>
2. The full guidance on extracorporeal membrane oxygenation in postneonatal children can be found at <http://www.nice.org.uk/IPG038guidance>
3. The full guidance on radiofrequency volumetric tissue reduction for turbinate hypertrophy can be found at <http://www.nice.org.uk/IPG036guidance>
4. The full guidance on transilluminated powered phlebectomy for varicose veins can be found at <http://www.nice.org.uk/IPG037guidance>
5. The full guidance on extracorporeal membrane oxygenation (ECMO) in adults can be found at <http://www.nice.org.uk/IPG039guidance>

About interventional procedures

6. NICE has assumed responsibility for developing guidance about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use.
7. An interventional procedure is a procedure used for diagnosis or treatment that involves one of the following:
 - making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel
 - gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth
 - using electromagnetic energy (which includes X-rays, lasers, gamma-rays and ultraviolet light) or ultrasound – for example, using a laser to treat eye problems.
8. NICE guidance on interventional procedures is developed by an independent advisory committee made up of professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Further information about the process that the committee follows when developing guidance can be accessed by visiting the NICE web site at <http://www.nice.org.uk/docref.asp?d=57369>.
9. Although many of the procedures the programme investigates are new, NICE also scrutinises more established procedures where there is uncertainty about patient safety and efficacy. NICE will alert the National Patient Safety Agency (NPSA) where concerns are raised about a specific procedure during the development of NICE guidance, and the NPSA will refer procedures to NICE for investigation when concerns are raised through the systems for long-term monitoring of adverse events which the NPSA plans to introduce later in 2003.

About NICE

NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit www.nice.org.uk.

10. NICE produces guidance in three areas of health:
 - the use of new and existing medicines and treatments within the NHS in England and Wales – technology appraisals
 - the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
 - whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use– interventional procedures.
11. NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).
12. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.