

PRESS RELEASE

NICE launches Interventional Procedures Guidance to protect patients and support health professionals when performing innovative surgical procedures

The National Institute for Clinical Excellence (NICE) is today launching eight 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 **deep brain stimulation for Parkinson's disease** appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.
 - The clinical and cost effectiveness of deep brain stimulation for Parkinson's disease is being evaluated by the PD Surg trial, which is expected to complete randomisation in 2005/6. The results of this trial are likely to provide evidence on the most appropriate use of the procedure and clinicians are encouraged to consider randomising patients in the trial (www.ihf.ox.ac.uk/herc/research/trials/pdsurg.shtml).
 - It is recommended that patient selection should be made with the involvement of a multidisciplinary team, and that patients should be offered the procedure only when their disease has become refractory to best medical treatment.
- Current evidence on the safety and short term efficacy of **holmium laser prostatectomy** appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance. Clinicians undertaking this procedure require specialist training. The British Association of Urological Surgeons has agreed to produce training standards.

- Current evidence on the safety and efficacy of **extracorporeal shockwave lithotripsy for calcific tendonitis of the shoulder** appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.
- Current evidence on the safety and efficacy of **endoscopic stapling of pharyngeal pouch** appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.
- Current evidence of the safety and efficacy of **bone-anchored cystourethropexy** does **not** appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake bone-anchored cystourethropexy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. In particular patients should be informed that the long-term efficacy of the procedures appears to be poor. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate 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 at present.
- Current evidence on the safety and efficacy of **balloon kyphoplasty for vertebral compression fractures** does **not** appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Although the benefits and risks of this procedure appear similar to those for percutaneous vertebroplasty in the first few months after the procedure is carried out, there is insufficient long-term evidence to substantiate this at present. Clinicians wishing to undertake balloon kyphoplasty for vertebral compression fractures should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's 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 at present. The following are recommended:
 - This procedure should only be undertaken when there are arrangements for good access to a spinal surgery service, and with prior discussion between a specialist multidisciplinary team that includes a radiologist and a spinal surgeon.

- Clinicians should receive training to reach an appropriate level of expertise before carrying out this procedure. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of embolisation.
- The procedure should be limited to patients whose pain is refractory to more conservative treatment.
- Current evidence on the safety and efficacy of **laparoscopic laser myomectomy** does **not** appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic laser myomectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's 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 at present.
 - Clinicians undertaking this procedure should undergo training as recommended by the Royal College of Obstetricians and Gynaecologists Working Party on Training in Endoscopic Surgery (www.rcog.org.uk).
- Current evidence on the safety and efficacy of **laparoscopic radical hysterectomy** does **not** appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laparoscopic radical hysterectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's 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 longer-term efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking any further investigation at present.
 - Clinicians undertaking this procedure should undergo training as recommended by the Royal College of Obstetricians and Gynaecologists Working Party on Training in Endoscopic Surgery (www.rcog.org.uk).

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 eight procedures: four procedures where

we have been advised that the data appears adequate to support their use; and four procedures where we have been advised there is uncertainty. Where such uncertainty exists we advise the NHS that patients are kept fully informed and that clinicians 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 **holmium laser prosectomy** can be found at <http://www.nice.org.uk/IPG017guidance>
2. The full guidance on **deep brain stimulation for Parkinson’s disease** can be found at <http://www.nice.org.uk/IPG019guidance>
3. The full guidance on **extracorporeal shockwave lithotripsy for calcific tendonitis of the shoulder** can be found at <http://www.nice.org.uk/IPG021guidance>
4. The full guidance on **endoscopic stapling of pharyngeal pouch** can be found at <http://www.nice.org.uk/IPG022guidance>
5. The full guidance on **bone-anchored cystourethropexy** can be found at <http://www.nice.org.uk/IPG018guidance>
6. The full guidance on **balloon kyphoplasty for vertebral compression fractures** can be found at <http://www.nice.org.uk/IPG020guidance>
7. The full guidance on **laparoscopic laser myomectomy** can be found at <http://www.nice.org.uk/IPG023guidance>
8. The full guidance on **laparoscopic radical hysterectomy** can be found at <http://www.nice.org.uk/IPG024guidance>

About NICE

9. 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.

About interventional procedures

13. 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.
14. 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.
15. 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>.
16. 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.