

## **PRESS RELEASE**

### **NICE welcomes Health Service Circular to help support health professionals and protect patients when introducing new surgical procedures**

The National Institute for Clinical Excellence (NICE) today welcomes the issuing of a Health Service Circular (HSC) informing the NHS how to engage with the Institute's Interventional procedures programme.

The HSC explains to the NHS that medical practitioners planning to undertake new interventional procedures (except in emergencies or when the procedure is being used only within a protocol approved by a Research Ethics Committee) must now seek approval from their NHS Trust's Clinical Governance Committee before doing so. The Chair of the Clinical Governance Committee should check to see if the procedure has been notified to the Interventional Procedures Programme at NICE and the medical practitioner should follow any guidance already issued on that procedure.

The Interventional Procedures Programme assesses whether interventional procedures – including procedures used for diagnosis or treatment that involve making a cut or hole in the body, entry into a body cavity or using electromagnetic energy (including X-rays or lasers) or ultrasound – are safe enough and work well enough for routine use in the NHS. The programme was introduced in response to concerns set out in the Bristol Royal Infirmary Report (Kennedy Report) and aims to protect the safety of patients and support clinicians, Clinical Governance Committees and the NHS as a whole in the process of managing and introducing procedures.

The HSC states that :

- Any doctor considering use in the NHS of a new interventional procedure which he/she has not used before, or only used outside the NHS, should seek the prior approval of their NHS Trust's Clinical Governance Committee. If the procedure is the subject of NICE guidance, the committee should consider whether the proposed use of the procedure complies with the guidance before approving it.
- If no NICE guidance on the procedure is available, the Committee should only approve its use if:
  - the doctor has met externally set standards of training,
  - all patients offered the procedure are made aware of the special status of the procedure and the lack of experience of its use. This should be done as part of the consent process and should be clearly recorded,
  - the Committee is satisfied that the proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that will be used to review continued use of the procedure.
- The Committee should also take account of the Clinical Negligence Scheme for Trusts standard 5.2.6.

**Dr Tom Dent, Director of the Interventional Procedures Programme** says “We are delighted the Department of Health has issued this HSC as it clarifies the status of NICE Interventional Procedures guidance and provides clear direction to NHS on the processes they should now follow when introducing new procedures. We recognise that the success of the Interventional Procedures Programme is dependent on appropriate engagement from the NHS and we are particular pleased that the HSC states that the Commission for Health Improvement (soon to become the Commission for Health Audit and Inspection) will assess how well clinical governance is working in Trusts by, amongst other things, how Trusts' Clinical Governance Committees introduce new interventional procedures.”

The Welsh Assembly Government has issued a similar circular to the NHS in Wales.

**Ends**

## Notes to Editors

1. The full Health Service Circular can be found on the Department of Health's website at :  
<http://www.info.doh.gov.uk/doh/coin4.nsf/Circulars?ReadForm>

## About NICE

2. 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](http://www.nice.org.uk).
3. 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.
4. 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).
5. 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

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/cat.asp?c=31122>
9. Although many of the procedures the programme will investigate are new, NICE will also scrutinise 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 their systems for long-term monitoring of adverse events.