



***National Institute for
Clinical Excellence***

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PRESS RELEASE

New NHS programme launched in Scotland to protect patients and support doctors when introducing innovative surgical procedures

A new programme to assess whether interventional procedures – including surgical operations and other 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 in Scotland is being launched today by the National Institute for Clinical Excellence (NICE), NHS Quality Improvement Scotland and the Scottish Executive.

The interventional procedures programme was introduced in England and Wales in February 2003 in response to concerns set out in the Bristol Royal Infirmary Report (Kennedy Report) and a need to develop better systems to ensure patient safety. Now patients and the NHS in Scotland are set to benefit from the programme. The programme will encourage innovation, protect the safety of patients and support clinicians, healthcare organisations and the NHS as a whole in the process of introducing new procedures.

The Scottish Executive is issuing a Health Department Letter to the NHS in Scotland informing them of how the programme will operate. Under the programme, healthcare professionals are responsible for notifying NICE when considering use of

a procedure that they have not used before, or have only used outside the NHS, and for applying any guidance on existing procedures to meet the needs of individual patients. The new programme means that patients will have better information before deciding whether to undergo a new procedure and healthcare professionals will be supported when introducing new procedures. The programme will encourage innovation by facilitating data collection and analysis, conducting rapid reviews and providing advice on the safety and efficacy of new procedures.

Professor Bruce Campbell, Chair of the Interventional Procedures Advisory Committee, said: “We are delighted to be working with our colleagues in Scotland to ensure that more people can benefit from this new programme. The programme will help to reassure patients and their carers that new procedures are being monitored to protect their safety. We will also promote good information for patients about risks and benefits. At the same time we want to encourage innovation and to get new procedures to patients who need them throughout the health service.”

Healthcare professionals who wish to undertake a procedure during the period between notification to NICE and the issuing of guidance on a topic should inform their hospital of their intention and inform patients of the uncertainty around the procedure’s safety and efficacy.

Guidance on interventional procedures is developed by an independent Interventional Procedures Advisory Committee which includes professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The committee takes advice from Specialist Advisors nominated by professional bodies with members who are involved in the use of interventional procedures, and will consult publicly on all guidance before it is issued.

The consultation document, and final guidance, will state whether current evidence indicates that:

- safety and efficacy appears adequate for use with the normal arrangements for consent, audit and clinical governance;
- the procedure is not safe and efficacious enough for use – in these cases, NICE will inform the Scottish Executive, Department for Health, Welsh Assembly

Government and National Patient Safety Agency (NPSA) of any concerns raised during guidance development;

- the procedure should not be used without special arrangements for consent and audit or research – in these cases, clinicians should inform the clinical governance leads in their hospitals and ensure that patients are informed of the procedure's status.

Healthcare professionals (and others) can express an interest in a particular procedure or group of procedures through the NICE web site at www.nice.org.uk/ip. They, and the person who notified the procedure, will be sent electronic updates on the procedure's progress throughout the programme and will be alerted when consultation documents are published. Further information about the process that the advisory committee will follow when developing guidance can be accessed by visiting the NICE web site at <http://www.nice.org.uk/docref.asp?d=57369>.

Ends

For more information contact Fraser Woodward at NICE on 020 7067 5905 or 07879 846787.

Notes to Editors

About NICE

1. 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. 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.
2. 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 in the NHS in England, Wales and Scotland – interventional procedures.
3. 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).
4. 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

5. NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use.
6. 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.
7. 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>.
8. Although many of the procedures the programme investigates are new, the programme 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 its systems for long-term monitoring of adverse events.
9. The Health Department Letter being sent to the NHS in Scotland will shortly be available on the web at www.show.scot.nhs.uk/sehd/hdl.asp.