



Health Department
Directorate of Service Policy and Planning

Health Planning and Quality Division
St Andrew's House
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Dear Colleague

Introduction

This letter advises that clinicians planning to undertake new interventional procedures (see definition in paragraph 17) should seek approval from their organisation's Clinical Governance Committee before doing so. The Chair of the Clinical Governance Committee should notify the procedure to the Interventional Procedures Programme (IPP) at the National Institute of Clinical Excellence's (NICE) website unless it is listed there www.nice.org.uk/ip (see paragraph 7).

In a case where the procedure has to be used in an emergency (see paragraph 12) the procedure should be notified to the Clinical Governance Committee within 72 hours.

The only exception to this process is where a procedure is being used only within a protocol approved by a Research Ethics Committee (see paragraph 14).

NHS Boards and Trusts should also support the collection of audit and research data on interventional procedures being reviewed by NICE.

Background

The safety and efficacy of new interventional procedures in the UK were previously assessed by SERNIP. A UK-wide review recommended that the pilot system needed stronger and more formal links to clinical governance and should be relocated within NICE.

Purpose of the Programme

NICE's Interventional Procedures Programme now covers Scotland as well as England and Wales. It assesses the safety and efficacy of interventional procedures. The programme's aims are to protect the safety of patients and to support doctors,

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Addresses

For action

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For information

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other clinicians, Clinical Governance committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly.

How the programme works

Clinicians and others intending to carry out a new interventional procedure should seek the approval of their organisation's Clinical Governance committee. If the procedure is not listed on NICE's website (www.nice.org.uk/ip), the Chair of the committee should ensure that NICE are notified of the procedure via the website. This will initiate the following procedure:

- NICE will prepare a brief overview of the evidence on the procedure's safety and efficacy, and consult its Specialist Advisors
- a NICE advisory committee will decide either to issue guidance on the procedure or to seek more information before doing so. As part of this process, NICE may commission a systematic review of research on the procedure, or set up a national register to collect data about patients who have been treated with the procedure
- NICE consults publicly on all guidance and its advisory committee will consider the responses before guidance on the procedure is issued.

Patients, managers and others can also notify procedures directly to NICE through the website.

What NHS Boards should do

When a clinician is considering using a new interventional procedure

The ability of the Interventional Procedures Programme to achieve its aims is dependent on appropriate engagement from the NHS Scotland.

A clinician considering use in NHS Scotland of a new interventional procedure which he/she has not used before, or used only outside the NHS, should seek the prior approval of their organisation'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.

When there is no existing nice guidance on the procedure being considered

If no NICE guidance on the procedure is available, the Committee should only approve its use if:

- the clinician 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. Patients need to understand that the procedure's safety and efficacy is uncertain and be informed about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment

- 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.

It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use a new procedure in a clinical emergency so as not to place a patient at serious risk. If a doctor has performed a new interventional procedure in such circumstances he/she must inform the Clinical Governance Committee within 72 hours. The Committee should then consider approval of the procedure for future use following the process set out above.

When NHS Board have authorised the use of a new interventional procedure for which no NICE guidance exists.

When no guidance exists NICE will collect data under this programme. Clinicians should supply the information requested on every patient undergoing the procedure. NHS Boards should support this to enable the NHS to have access more speedily to guidance on the procedure's safety and efficacy. The collection of data from patients will be governed by the Data Protection Act.

The only exception to the above process is when the procedure is being used only within a protocol approved by a Research Ethics committee (REC). In this case, notification is not required, as patients are protected by the REC's scrutiny. However, RECs should notify the organisation's Clinical Governance committee when they approve a protocol involving an interventional procedure. Use of the procedure outside the protocol should only occur after approval from the Clinical Governance committee as set out above.

If an adverse incident occurs when the procedure is being undertaken, it should be reported in the normal way locally to the organisation's Risk Manager.

NHS Quality Improvement Scotland's future Generic Clinical Governance reviews will include a check on how well local Clinical Governance Committees have introduced new interventional procedures.

Definitions

An ***interventional procedure*** is one used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, electromagnetic energy or ultrasound.

An interventional procedure should be considered ***new*** if a doctor no longer in a training post is using it for the first time in his or her NHS clinical practice.

Associated Documentation

The IPP is run by NICE for England, Wales and Scotland. NHS Quality Improvement Scotland will liaise with NICE in connection with the management of the programme and NHS Scotland clinicians will serve on the Interventional Procedures Advisory Committee. Enquiries about the programme should be directed to IPP at NICE. If there are any specific enquiries related to Scotland's participation in IPP please contact Dr Harpreet S Kohli at NHS Quality Improvement Scotland (hkohli@htbs.org.uk or 0141 225 6991).

Yours sincerely

CHIEF MEDICAL OFFICER

CHIEF NURSING OFFICER