



Department of

**Health, Social Services
and Public Safety**

An Roinn

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Your Ref:

Our Ref: PPMD(NICE)1/07

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For action to:

Chairs and Chief Executives of HSS Trusts
Chairs and Chief Executives of HSS Boards

For cascade to:

Chairs of Committees with responsibility for CSCG/Risk Management
Executive Lead - Governance/C&SCG/Risk Management/Adverse Incident Management
Medical Directors in HSS Boards and Trusts
Directors of Public Health in HSS Boards
Directors of Nursing in HSS Boards and Trusts
Directors of Primary Care in HSS Boards and Community Trusts

For information to:

Chief Executive, Regulation and Quality Improvement Authority (RQIA) (for cascade to registered private hospitals and medical clinics)
Office of Research Ethics Committee (OREC)
Chief Officers, Health and Social Services Councils
Chief Executive, NI Medical Physics Agency
Chief Executive, NI Blood Transfusion Service
Head of School of Medicine and Dentistry, QUB
Head of School of Nursing and Midwifery, QUB
Head of School of Nursing, UU
Chief Executive/Post Graduate Dean, NIMDTA
Chief Executive, NIPEC
Chair, Area Medical Advisory Committees
Regional Governance and Risk Management Adviser
Director, Clinical and Social Care Governance Support Team

Dear Colleague

Working for a Healthier People



INVESTOR IN PEOPLE

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE: (NICE) THE INTERVENTIONAL PROCEDURES PROGRAMME

Introduction

1. Northern Ireland now participates in the NICE Interventional Procedures Programme and new arrangements have been developed for HPSS healthcare professionals intending to undertake new interventional procedures (see definition at paragraph 5). These arrangements came into effect on 1 January 2007.
2. This circular outlines the new arrangements and explains what clinicians need to do before performing an interventional procedure they have not used before in the HPSS. It also explains the role, within the new arrangements, of HSS Trust committees with responsibility for clinical and social care governance issues. Implementation of the new arrangements will bring the HPSS into line with the NHS in England, Scotland and Wales in terms of the availability of structured support for the introduction of clinical innovation.

Background

3. On 1 July 2006, the Department agreed a formal link with NICE which enables the Department and the HPSS to participate in the Institute's technology appraisal, clinical guideline, and interventional procedures programmes. Northern Ireland has joined with England, Scotland and Wales as full participants in the Interventional Procedures Programme, and HPSS organisations are now expected to take into account the Institute's guidance in this area.
4. The NICE Interventional Procedures Programme assesses the safety and efficacy of new interventional procedures. It aims to protect the safety of patients and to support clinicians, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly. It is designed to be responsive and to produce succinct guidance within a relatively short (approximately 40 weeks) timescale.

Definition of an "interventional procedure"

5. An **interventional procedure** is defined as any procedure used for diagnosis or treatment that involves incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy. Most interventional procedures are undertaken within the secondary care sector and many of them are surgical. However, there is potential for new, innovative interventional procedures to be delivered in other HPSS settings and the Programme is therefore relevant to all clinical settings.
6. An interventional procedure should be considered **new** if it is not in regular use and a clinician, no longer in a training post, is using it for the first time in their HPSS clinical practice. Most innovations are modifications of existing techniques rather than being entirely new. In making decisions about what is

new, NICE therefore considers whether the notified procedure is novel, a minor variation on established practice, or well established. It also considers whether the innovation is likely to change the safety or the efficacy of what is being done. While the Programme is concerned largely with new procedures, it may also assess established procedures if there is concern about their safety and/or efficacy.

How the Programme works within the NHS

7. New interventional procedures are notified primarily by clinicians who want to use them for the first time within the NHS. Clinicians notify NICE through their Trust's clinical governance structures. Patients, professional organisations, manufacturers, and any other interested person can also notify procedures directly to the Institute through its website.
8. A notification initiates the following process:
 - NICE checks to ensure the notification is appropriate to the Programme and does not duplicate an existing notification. Interventional procedures will not fall within the scope of the Programme if they are considered standard clinical practice with benefits and risks that are sufficiently well known.
 - NICE prepares a brief overview of the evidence on the procedure's safety and efficacy and requests opinions from Specialist Advisors (who have been nominated by professional organisations such as the Royal Colleges).
 - The Institute's Interventional Procedures Advisory Committee (IPAC) considers the Advisors' comments, together with the overview, and decides whether the procedure is efficacious and safe for routine use, or whether any restrictions should apply. IPAC also decides whether to issue guidance on the procedure or to seek more information before doing so.
 - NICE posts the draft guidance on its website for a four week period of public consultation. Key stakeholder organisations and everyone who has registered an interest in the procedure, or in that general area of work, are notified that consultation is starting.
 - NICE publishes its final guidance on the procedure and circulates this to all relevant clinicians, governance leads, chief executives, medical directors, etc. In addition, anyone can request automatic E-mail alerts about the publication of guidance in any area they choose, or can arrange to receive guidance directly.
9. Interventional procedure guidance is very brief and usually runs to no more than two sides of an A4 page. The guidance generally states whether current evidence indicates that:

- the procedure is safe and efficacious for routine use in the NHS; or
- the procedure is not safe and efficacious for routine use; or
- there is inadequate evidence for a judgement about safety and/or efficacy, and the procedure should not be used without special arrangements for consent, audit or research.

The guidance may also make recommendations on the experience, training and facilities needed by clinicians undertaking the procedure.

10. Interventional procedure guidance is concerned only with safety and efficacy; there is no consideration of cost or cost-effectiveness. It simply recommends the circumstances in which a procedure should be used and confirms that the procedure does what it is intended to do. It does not recommend that the procedure ought to be used, or that it ought to be funded.
11. The Institute does not routinely reconsider interventional procedure guidance as the increasing volume of procedures would make this unmanageable. However, suggestions for review of guidance from any source are considered when new information is presented that calls into question the validity of current guidance.

What the HPSS should do

12. Any clinician in Northern Ireland considering using in the HPSS a new interventional procedure which they have not used before, or only used outside the HPSS/NHS, should seek the prior approval of their Trust's Committee with responsibility for clinical and social care governance issues ("**the Committee**"). Clinicians, such as GPs with special interests working in HPSS settings outside of the secondary care sector, should follow similar principles and report their intention to perform a new procedure to the employing or contracting organisation.
13. On receipt of an approval request from a clinician, the Committee Chair should check the NICE website www.nice.org.uk to find out what guidance, if any, has been issued or whether the procedure is listed as having already been notified to NICE. If the procedure is the subject of NICE guidance, the Committee should consider whether the clinician's proposed use of the procedure complies with the guidance before giving its approval.
14. Where a procedure is not listed on the NICE website, the Chair of the Committee should notify the procedure to NICE via the Institute's website and inform the Department by e-mail via the Standards & Guidelines NICE inbox: sgu-niceguidance@dhsspsni.gov.uk
15. Where a procedure has not previously been notified to NICE, or where it is listed but guidance has not yet been developed, the Committee should only approve the procedure in the interim if:
 - The clinician has met externally set standards of training.

- 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. NICE issues audit criteria for certain specific pieces of guidance that may be used for this purpose.
 - The Committee is satisfied that adequate clinical and social care governance arrangements are in place to ensure appropriate management of risks, complaints, negligence and redress.
16. Clinicians who are approved by their Committees to undertake a procedure, during the period between notification to NICE and the issuing of guidance on a topic, should inform their Medical Director of their intention. All patients offered the procedure should be made aware of the lack of experience of its use and of the uncertainty around its safety and efficacy. They should also be informed about the anticipated benefits, and possible adverse effects of the procedure, and of alternatives (including no treatment). This should be done as part of the consent process and should be clearly recorded.
17. Where the Institute is collecting data under the Programme to help inform the development of guidance on a procedure, clinicians should supply the information requested on every patient undergoing the procedure. HSS Trusts are encouraged to support the supply of this information to NICE. It should be noted that the collection of data from patients will be governed by the Data Protection Act.

Exceptions

18. Where a procedure is being used strictly within a protocol approved by an HPSS/NHS Research Ethics Committee, notification to NICE is not required. In these circumstances, patients are protected by the Research Ethics Committee scrutiny.
19. 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. Clinicians do not therefore need to seek the approval of their Committee in emergencies. However, where a clinician has performed a new interventional procedure in such circumstances, they must inform their Committee within 72 hours. The Committee should then consider approval of the procedure for future use as above and notify NICE of the procedure.

Dissemination of guidance to the HPSS

20. The Department will disseminate NICE guidance on interventional procedures to HPSS organisations. Clinicians in Northern Ireland are encouraged to register an interest on the NICE website in order to receive updates on the development of interventional procedure guidance relevant to their HPSS practice.

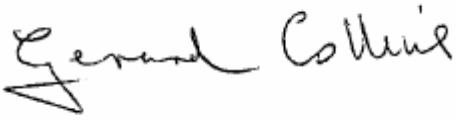
Monitoring

21. The Quality Standards for Health and Social Care (published by the Department in March 2006) make specific reference to the need for new interventional procedures to be supported by evidence on safety and efficacy. These Standards will be used by the Regulation & Quality Improvement Authority to assess the governance arrangements and the quality of care provided or commissioned by HPSS organisations. As part of its clinical and social care governance inspections, the Regulation and Quality Improvement Authority may, therefore, assess how well HPSS organisations have introduced new interventional procedures.
22. If an adverse incident or near miss occurs when a new interventional procedure is carried out, this should be reported and managed through the HPSS organisation's established adverse incident reporting and management systems. Criterion 4 of the Risk Management Controls Assurance Standard provides guidance on the elements required for the management of adverse incidents. Guidance on how to classify adverse incidents and risks was issued in April 2006 in HSS (MD) 12/2006. This document provides a useful guide for senior managers responsible for assessing adverse incidents and their risk implications.
23. Where a serious adverse incident occurs - which meets the criteria set out at paragraph 16 of HSS (PPM) 06/04 - it should be reported to the Department in accordance with the guidance set out in HSS (PPM) 02/06.

Further information

24. The Interventional Procedures Programme is run by NICE for the UK. HPSS healthcare professionals will therefore have an opportunity to nominate to serve as Special Advisors and on the Interventional Procedures Advisory Committee.
25. Further information on the Interventional Procedures Programme can be found on the NICE website www.nice.org.uk. Enquiries about the Programme should be directed to the Programme coordinators at ip@nice.org.uk.
26. This guidance will be reviewed in 2008 to take account of changes in local health service provision, structures and national developments. Any queries relating to this circular, or about Northern Ireland's participation in the Programme, should be directed to Mary McStay, Standards and Guidelines Unit, D2.4, Castle Buildings, Stormont, Belfast, BT4 3SQ, telephone (028) 9052 2207 or e-mail mary.mcstay@dhsspsni.gov.uk.

Yours sincerely

A handwritten signature in black ink that reads "Gerard Collins". The signature is written in a cursive style with a large, stylized initial 'G'.

Gerard Collins

Head of Standards and Guidelines Unit