

POLICY / PROCEDURE FOR CLINICIANS ON IMPLEMENTING NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE) GUIDANCE ON USING NEW INTERVENTIONAL PROCEDURES

Author (s): Clinical Policy Advisor, Associate Medical Director

Version: 9

Status: Approved

Authorised by: Clinical Policy Documentation and Information Group

Date of Authorisation: 2015

Review Date: 2018

Key Words: new interventional procedures

Comments:

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1. Introduction / Background

The safety and efficacy of new interventional procedures in the UK were previously assessed by the Safety and Efficacy Register for New Interventional Procedures (SERNIP). A UK-wide review recommended that the pilot system needed stronger and more formal links to clinical governance and should be relocated within the National Institute for Health and Clinical Excellence (NICE).

In January 2004, Scotland became a full participant in the Interventional Procedures Programme (IPP) and Scotland is included in the circulation of IPP guidance directly from NICE (See NHS HDL (2004) 04).

This HDL states that no new interventional procedure can be implemented without notification to and approval from the Clinical Governance Committee.

NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use.

NICE's Interventional Procedures Programme remit is to:

- Assess the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately.
- Enable clinical innovation to be conducted responsibly, by reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the efficacy and safety of interventions. No interventional procedure is entirely free from risk, but the IPP gauges the extent of uncertainties and makes recommendations on their implications.
- Issue guidance on interventional procedures to help ensure that:
 - patients and carers are reassured that new interventional procedures are being monitored and reviewed to protect patient safety, and that they have access to information about procedures
 - clinicians, healthcare organisations and the NHS as a whole are supported in the process of introducing new procedures
 - innovation is fostered by providing advice on the efficacy and safety of new procedures, recommending training and other conditions for their use in the NHS, facilitating data collection and analysis, and arranging systematic reviews.

Nearly all the procedures that the IPP investigates are not well established in clinical practice, but the IPP can also scrutinise more established procedures if there is reason to be uncertain about their efficacy and/or safety.

To fall within the remit of the IPP, a notified interventional procedure must:

- Involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy, and
- be available within the NHS or be about to be used for the first time in the NHS, outside formal research, and
- be either not yet generally considered standard clinical practice or a standard clinical procedure, the safety or efficacy of which has been called into question by new information.

(Extracted from NICE IPP process guide 2009 and IPP methods guide 2007).

2. Definition of an Interventional Procedure

An **interventional procedure** is one used for diagnosis or treatment that involves:

- incision, puncture, entry into a body cavity e.g. when carrying out an operation, inserting a tube into a blood vessel, endoscopy; or
- the use of ionising, electromagnetic or acoustic energy e.g. X-rays, lasers, gamma-rays and ultraviolet light.

This definition would also cover the insertion of an implant.

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

If a procedure is established clinical practice in NHS Lothian but **new** to a clinician, the Clinical Director must verify the individual has met the required standards of training and competence.

3. Aim of the Policy

To protect the safety of patients, reduce risk to the organisation and support clinicians in the development and implementation of new interventional procedures.

4. Scope of the Policy

The definition of a clinician is any registered practitioner and therefore this policy is applicable across NHS Lothian to Medical Staff, Nursing Staff, Allied Healthcare Professionals and Clinical Scientists.

5. The Procedure

5.1 Local Level

A clinician considering the use in NHS Lothian of a new interventional procedure which he/she has not used before, or used only outside the NHS, should discuss it locally with the Clinical Director/Clinical Management Team and seek the provisional approval of the local Clinical Governance Committee i.e. the UHSS Clinical Management Group or CHP Clinical Governance and Risk Management Committee. This will include development and signed approval of a business case, which clearly details the estimated budget and other resource requirements.

The clinician should consult the NICE website <http://www.nice.org.uk/> to ascertain if the procedure is already listed and subject to NICE guidance.

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 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 (See NHS Lothian Consent Policy 2010 for details including information on Adults with Incapacity, Children and Patients Detained under the Mental Health Act). 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.

The Committee should then make a recommendation if the procedure should proceed to the Medical Director (MD) who will note this at the next available Board Healthcare committee.

5.2 NHS Lothian Level

New procedures should have approval from the relevant Clinical Management Team (CMT) with a supporting business case. Additionally, the new interventional procedure should have been considered and approved, provisionally, by the University Hospitals and Support Services (UHSS) or Health and Social Care Partnerships (HSCP) HGRM group. See above 5.1

Following final approval of the new procedure this intervention should be notified to the IPP at the NICE website, unless it is already listed on their website <http://www.nice.org.uk/>

NHS Boards are required to support the collection of audit and research data on interventional procedures being reviewed by NICE; this means that NHS Lothian must know who is performing new or innovative procedures to ensure that the necessary data is sent to NICE.

The only exception to this process is where a procedure is being used within a protocol already approved by a Research Ethics Committee and the study has Management Approval.

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 rapid access guidance on the procedure's safety and efficacy. The collection of data from patients will be governed by the Data Protection Act.

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

6. Roles and Responsibilities

6.1 Responsibility of presenting clinician

Any clinician considering the use of a new interventional procedure which he/she has not used before, or used only outside the NHS, must:

- In the first instance discuss the proposal with their Clinical Director*
- * Depending on the profession involved replace Clinical Director with Associate Nurse Director/Allied Health Professional (AHP) Lead as appropriate. (See also appendix 1)
- Provide information, including an accompanying business case, pertaining to the new interventional procedure to their Clinical Director (see also section 5.1)
- Demonstrate that he/she has met externally set standards of training prior to securing approval from their Clinical Director for the introduction of a new procedure.
- Seek agreement for the development of the procedure with the clinical management team (CMT) and Director of Operations, including written confirmation of available budget/resources and consideration of :
 - Impact in terms of training, review of performance and accountability of other staff involved in the care of a patient undergoing a new interventional procedure
 - Any ethical considerations
- Not introduce the new procedure until final approval has been given by the NHS Lothian HGRM Committee.

See also Appendix 2

Prior to and following implementation:

- Abide by NICE guidance when issued.
- Collect and supply information requested on every patient who has undergone this new interventional procedure.
- Ensure all patients offered the new procedures are fully informed of its innovative nature and give fully informed consent to its use.

6.2 Responsibility of the Clinical Director

The Clinical Director in receipt of a proposed new interventional procedure will:

- Assess whether the procedure complies with NICE guidance.
- Ensure that proposed new interventional procedures **not covered by NICE guidance** are notified to NICE through the website either by self or by the relevant clinician. NICE will prepare a brief review of the evidence and consult specialist advisers. An Advisory Committee of NICE will decide either to issue guidance or to seek more information, and may commission the systematic review of research or set up a national register.
- Assess the requirement for the proposed new interventional procedure.
- Assess whether it will be supporting the objectives of NHS Lothian either through service delivery, teaching and training, or research.
- Consult with the relative Site or Support Services Director.. If budget/resource availability is confirmed forward the information to the Associate Divisional Medical

Director for consideration at the UHS Clinical Management Group or HSCP HGRM group prior to submitting for final approval to the NHS Lothian HGRM Committee.

- Clinical Directors will review the training and competency of those undertaking the listed procedures: Clinical Directors should satisfy themselves that the relevant clinicians, including members of the wider clinical team who may be involved in the new procedure, have undertaken approved or appropriate training and can demonstrate the required skills. Where they have any doubt they should discuss this with their Associate Medical Director as a matter of urgency.
- Clinical Directors will compile the names of clinicians undertaking the procedures being reviewed by NICE and send this information to the Associate Medical Director (Associate Nurse Director or AHP Lead if appropriate) or, in the case of HSCPs, to the Board Medical Director (Nurse Director or AHP Director if appropriate).
- The Clinical Director must ensure a clinical audit programme is in place that will capture the data on outcomes and adverse effects that will be used to review continued use of the procedure.

6.3 Responsibility of Medical Director of UHSS for proposals from University Hospitals Services and Board Medical Director for proposals from HSCPs

- The Medical Director of UHSS will receive from the Clinical Director or Associate Medical Director details of any proposed new interventional procedure; assess the requirement for the new interventional procedure, and whether the use of the procedure complies with the relevant NICE guidance.
- The Board Medical Director will receive information from the Medical Director of UHSS, and / or the Clinical Director for HSCPs on new interventional procedures for which approval is sought.
- The Associate Medical Director or Medical Director will ensure that new proposed interventional procedures **not** covered by NICE guidance have been notified to NICE through the website by the relevant Clinical Director or clinician. See 5.2.
- Where it is not clear that the clinician has acquired the competence to undertake one of these listed procedures, the Medical Director or Associate Medical Director will seek specialist advice from NICE or from the relevant Royal College or Specialty Association.
- The Medical Director or Associate Medical Director will forward information to the Clinical Director with regard to their requirements for clinical audit and data collection.
- The Medical Director or Associate Medical Director will make a recommendation to the NHS Lothian HGRM Committee as to whether to approve a new interventional procedure in Lothian. The NHS Lothian HGRM Committee may accept the recommendation, reject it or seek further advice.
- The Board Medical Director will create a register of this information and forward to NICE.
- The Board Medical Director will maintain a database of approved procedures, along with the names of clinicians undertaking the procedures, which will be reviewed regularly by the NHS Lothian HGRM Committee.

7. In the Case of an Urgent Indication

The Board Medical Director or UHSS Medical Director after consultation with the Chief Executive or Chief Officer and the Chair of the NHS Lothian HGRM Committee, may grant approval for limited use in the circumstances of an urgent indication, until the full Committee can meet and approve a recommendation.

8. Exemption

It is acknowledged 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 clinician has performed a new interventional procedure in such circumstances, he/she must inform the UHSS Medical Director or Board Medical Director, within 72 hours. Where the procedure has been carried out as an emergency, the clinician should seek approval of the procedure for future use as per the agreed process.

9. Research Ethics Committee

The Research Ethics Committee Chair will notify the Board Medical Director of a research protocol approved, which involves any new interventional procedure. The Board Medical Director will inform the NHS Lothian HGRM Committee of this action and the committee will decide whether or not to give management approval for the study to take place.

10. Evidence Base/Sources of Information

<http://www.nice.org.uk/> Accessed: 19/01/11

Kohli, H., Tannahill, A., NICE Guidance in the Scottish Context ***Scottish Medical Journal Vol 54 Issue 1*** February 2009

National Institute for Health and Clinical Excellence (2007) ***Interventional Procedures Programme Methods Guide***

National Institute for Health and Clinical Excellence (2009) ***Interventional Procedures Programme Process Guide***

NHS Lothian (2014) ***Policy and Guidance for Obtaining Consent***

NHS Scotland (2004) ***Health Department Letter 2004 04*** NHS Scotland, Edinburgh

Appendix 1

Proposal for approval of new interventional procedure. Information required:

Procedure name:

Clinician proposing:

Clinical Director supporting:

Director of Operations/Clinical Management Team supporting:

Clinical Directorate:

NICE Guidance reference and date:

Description of procedure:

Clinician(s) who will undertake:

Other centres undertaking in Scotland/UK:

Audit arrangements:

Approved Business Case attached:

Evidence of Training undertaken attached:

Appendix 2

NHS Lothian New Interventional Procedures Flowchart

Step by Step Procedure for Presenting Clinician

