

New Interventional Procedures- Application Process for use in NHS Lothian

Introduction of new interventional procedures is subject to **NICE's Interventional Procedures Programme** which covers Scotland as well as England and Wales. It assesses the safety and efficacy of interventional procedures to determine whether they work well enough and are safe enough for use in the NHS. The programme's aims are to protect the safety of patients and to support doctors, other clinicians, Clinical Governance Committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly.

Research: This application process does not cover new procedures being done as part of any research project which should be subject to approval through Research Ethics Committees.

Scottish Government **DL (2017)10 8 May 2017** sets out requirements for health boards in Scotland in relation to new interventional procedures.

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

- 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, or
- 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, or
- using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

Many of the procedures that NICE investigates are new, but they also look at more established procedures if there is uncertainty about their safety or how well they work.

Guidance at:

<https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance>

NICE has 4 levels of recommendation for these procedures following evaluation: (see NICE website for details of each level)

1. Use with **standard arrangements** for clinical governance, consent and audit
2. Use with **special arrangements** for clinical governance, consent and audit
3. Use only in **research**
4. Do not use

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Process for Application to use a NEW Interventional Procedure in NHS Lothian:

1. Clinician applicant seeks support from service Associate Medical Director and Clinical Management Team to introduce a new procedure. This should include a plan for funding and may need a business case.
2. Clinician applicant checks if the procedure is in routine use elsewhere in the NHS or independent sector
3. Clinician applicant checks if the procedure is already subject to NICE interventional procedures programme (see NICE website) and their level of recommendation. If the procedure is “Out of Remit”, why is this?
4. If answer to 3 is “No”, applicant notifies NICE and awaits their recommendation.
5. Clinician applicant ensures that appropriate training and experience for all users is in place.
6. Clinician applicant ensures written clinical guidance is in place for all users including reporting of any adverse events through the Datix system.
7. Clinician applicant ensures that arrangements for appropriate audit of procedure and outcomes are in place. This may include review at applicant’s appraisal.
8. Clinician applicant ensures that arrangements are in place for consent to the procedure: All patients offered the procedure are made aware of any special status of the procedure in the NHS. This should be done as part of the consent and shared decision-making process, and should be clearly recorded.
9. Application form completed and sent for approval at NHS Lothian Clinical Management Group (Healthcare Governance Committee for University Hospitals and Support Services in NHS Lothian). This will involve personal presentation to CMG by the clinician applicant.
10. Decision by CMG for approval to use
11. Arrangements for review (time and/or number of procedures) by applicant, clinical management team and CMG agreed at CMG.

NHS Lothian Records:

A database of all applications, approval status, review and follow up arrangements will be held by the Medical Director for UHSS, NHS Lothian.

Accompanying Documents:

1. Scottish Government **DL (2017)10 8 May 2017**
2. NHS Lothian Application Form to use a New Interventional Procedure.