Lothian NHS Board

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Date: 11/09/2026
Our Ref: 11820
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Dear

FREEDOM OF INFORMATION – NEW INTERVENTIONAL PROCEDURES

I write in response to your request for information in relation to new interventional procedures in NHS Lothian.

Question:

1. Do you currently have a policy, standard operating procedure, framework, governance document or equivalent process that applies to the introduction, approval, oversight or monitoring of:
   - New interventional procedures;
   - Novel surgical procedures;
   - Innovative procedures; or
   - Procedures undertaken for the first time within your organisation?

Answer:

Yes. The New Interventional Procedures Policy is attached.

Question:

2. If such a document exists, please provide:
   - The title of the current document;
   - A copy of the document (PDF or Word format preferred);
   - The date on which the current version became effective, active, approved or implemented;
   - The date of the most recent review; and
   - The next scheduled review date (if applicable).

Answer:

The current New Interventional Procedures Policy became effective in January 2026 after a review period from November 2025. The next review is due prior to January 2029.

Question:

3. If your organisation uses a process that is not contained within a standalone policy document, please provide:
   - A description of the governance process used;

- Any associated approval forms, checklists, committee terms of reference or governance documentation used to assess and approve new procedures.

4. Please indicate whether your process specifically addresses any/all of the below:
   - New surgical procedures;
   - New interventional radiology procedures;
   - New endoscopy procedures;
   - New cardiology procedures;
   - Use of new devices or implants; and
   - Procedures undertaken as part of innovation, research, service development or service transformation.

Answer:

The standalone policy is used.

Question:

5. During the period **1 January 2023 to 1 January 2026**, please provide:
   - The total number of applications, proposals or approvals for new, novel or innovative interventional procedures considered through this process;
   - The number approved;
   - The number declined or not approved;
   - Where available, a breakdown by specialty (for example surgical speciality, interventional radiology, cardiology, endoscopy or other specialties).

Answer:

There have been 6 applications, all of which were approved. The applications were as follows:

Applications for New Interventional Procedures, 2023-2025, NHS Lothian		
Date	**Procedure**	**Specialty**
April 2023	Lateral Orbital Decompression	Ophthalmology
May 2023	Laser Ablation Service	Neurosurgery
February 2024	Hybrid Thoracoflo Device	Vascular surgery
November 2024	Thumb join replacement	Plastic surgery
December 2024	EVH Cardiac Surgery	Vascular surgery
October 2025	Flexible Endoscopic treatment for Zenkers diverticulum	GI Medicine

Question:

6. Please indicate:
   - Which committee, group or executive lead is responsible for approving new procedures within your organisation (title only).

Answer:

Acute Clinical Management Group.

Question:

7. Please state whether your organisation maintains a register, database, tracking system or log of approved new or innovative procedures and, if so, please provide:
   - A copy of the register or log (with any necessary redactions for personal information);
   - The procedure name or title;
   - The specialty involved;
   - The date of approval;
   - The current status (for example approved, piloted, implemented, suspended or withdrawn), where recorded.

Answer:

A copy of the register is enclosed.

Question:

8. Please indicate whether any new interventional procedures, surgical innovations or first-in-organisation procedures have been approved through an expedited, emergency or exceptional approval route (EG Chairs action) since 1 January 2023 and, if so, provide:
   - The procedure name;
   - The approving body; and
   - The year of approval.

Answer:

None have been approved through and exceptional approval route.

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at https://www.foi.scot/appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the reviewer at the address at the top of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI

Yours sincerely

ALISON MACDONALD
Executive Director of Nursing Midwifery and AHPs
Cc: Chief Executive
Enc.

New Interventional Procedures Policy

Title: New Interventional Procedures Policy			
Date effective from:	January 2026	**Review date:**	January 2029
Approved by:	Policy Approval Group		
Approval Date:	27 January 2026		
Author/s:	Deputy Medical Director, Standards and Governance		
Policy Owner:	Medical Directors Group		
Executive Lead:	Executive Medical Director		
Target Audience:	Clinical staff		
Supersedes:	New Interventional Procedures Policy v9 (2015)		
Keywords (min. 5):	Interventional procedure, radiation, implant, consent		

New Interventional Procedures Policy

Version Control

Date	Author	Version	Reason for change
2015	Associate Medical Director	v9.0	Approved by CPDIG
Nov 2025	Deputy Medical Director, Standards and Governance	v9.1-3	Under review
Jan 2026	Deputy Medical Director, Standards and Governance	v10.0	Approved by the Policy Approval Group

Executive Summary

This policy sets out the approach which should be taken to the introduction of new interventional procedures in NHS Lothian. The Lothian policy sits within the context of guidance from the Scottish Government DL(2017)10. This guidance references the National Institute for Health and Care Excellence (NICE) Interventional Procedures Programme (IPP) and describes how Scottish Health Boards should interact with that programme. This policy is based on the assumption that most new interventional procedures will be performed on a planned basis but allows flexibility for unscheduled and emergency procedures. The process, when new interventional procedures are performed as part of a formal research study, is described.

This policy should be read in conjunction with the NHS Lothian Consent Policy.

New Interventional Procedures Policy

NHS Lothian

Contents

1.0 Purpose

The purpose of this policy is to protect patients, support clinicians in the development and implementation of new interventional procedures and minimise risk to the organisation.

2.0 Policy statement

Within NHS Scotland, the Scottish Government Guidance DL(2017)10 superseded previous guidance on the introduction of new interventional procedures. The current guidance states that healthcare professionals wishing to carry out a new interventional procedure must always obtain approval using the appropriate governance structures within the organisation in which the procedure is to be performed.

Within NHS Lothian the appropriate governance will be provided either by Acute Clinical Management Group (ACMG), the relevant Health and Social Care Partnership (HSCP) Clinical Governance and Risk Management Committee, or the Royal Edinburgh and Associated Services (REAS) Clinical Governance and Risk Management Committee. These committees are referred to as the 'local committee' in this policy.

3.0 Scope

This policy applies to all registered practitioners working within NHS Lothian, including medical staff, nursing staff, Allied Healthcare Professionals and Clinical Scientists.

4.0 Definitions

Clinician: For the purposes of this policy the definition of a ***clinician*** is any registered practitioner, including medical staff, nursing staff, Allied Healthcare Professionals and Clinical Scientists.

Interventional Procedure: An ***interventional procedure*** is a procedure 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 also covers 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 their NHS clinical practice
- the indications for an established procedure are changed and/or extended to a new patient group.

If a procedure is established in clinical practice in NHS Lothian but new to a clinician, it will not be considered to be a new interventional procedure. However, the Clinical Director must verify the individual has met the required standards of training and competence.

Local committee: for the purposes of this policy, ***'local committee'*** refers to the Acute Clinical Management Group (ACMG), the relevant Health and Social Care Partnership (HSCP) Clinical Governance and Risk Management Committee, or the Royal Edinburgh and Associated Services (REAS) Clinical Governance and Risk Management Committee.

5.0 Roles and responsibilities

5.1 Approval Process

5.1.1 Clinical Management Team (CMT)

A clinician considering the use in NHS Lothian of a new interventional procedure which they have not used before, or used only outside the NHS, should discuss it locally with the Clinical Director and CMT, and complete a Proposal for approval of a New Interventional Procedure [Proposal for approval of a New Interventional Procedure] form to seek the provisional approval of the local committee.

The approval request must be accompanied by a business case which has been approved by the CMT and which clearly details the estimated costs and other resource requirements of introducing the new procedure.

5.1.2 The Local Committee

The local committee should only approve a new interventional procedure if:

- The clinician and supporting staff, such as nursing, radiography and operating theatre staff have completed any relevant training, e.g. as advised by NICE, the relevant Royal College or Specialty Association or the relevant manufacturer.
- Patients offered the procedure will be made aware of the status of the procedure and the limited experience of its use within NHS Lothian. This should be done as part of the consent process and should be clearly recorded (see the NHS Lothian Consent Policy). Patients must understand the anticipated benefits and possible risks of the procedure, and any alternatives, including no treatment
- The local committee is satisfied that the proposed arrangements for clinical audit are appropriate and will capture data on clinical outcomes that will be used to review continued use or discontinuation of the procedure.

The approval request must confirm whether or not the procedure is already listed and subject to NICE guidance http://www.nice.org.uk/ (see paragraph XX). If the procedure is the subject of NICE guidance, the local committee should consider whether the proposed use of the procedure complies with this guidance before approving it.

The local committee should:

- Be assured that the proposed arrangements for clinical audit are appropriate and will capture adequate data on clinical outcomes that will be used to review continued use or discontinuation of the procedure
- Include the new interventional procedure in its annual report to the NHS Lothian Board Healthcare Governance Committee.

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.

The local committee must agree a review period after which audit and outcome date will be reviewed to decide if:

1. the procedure remains a new interventional procedure
2. is discontinued in NHS Lothian, or
3. becomes a business-as-usual procedure subject to routine clinical governance oversight.

5.2 Individual members of staff

5.2.1 Requesting clinician

A clinician considering the use of a new interventional procedure which they have 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 Proposal for approval of a New Interventional Procedure)
- Seek agreement for the introduction of the procedure from the CMT and Director of Operations after
  - confirmation of available budget and resources
  - consideration of the 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
- Provide evidence that they, and supporting staff such as nursing, radiographer and operating theatre staff, have completed, or will complete, any relevant training prior to seeking approval from the local committee.
- Submit a request for approval using the form at Proposal for approval of a New Interventional Procedure [Proposal for approval of a New Interventional Procedure] along with the CMT business case, evidence of training for staff involved, with support from the Clinical Director* and Director of Operations.
- Not perform the new procedure until final approval has been given by the local committee.
- Prior to and following implementation:

- Ensure all patients offered the new procedures are fully informed of its innovative nature and give fully informed consent to its use.
- Collect and supply information requested on every patient who has undergone this new interventional procedure.
- Follow any relevant guidance from NICE.
- If an adverse event occurs during or after a new interventional procedure, it must be reported using the Datix system.

5.2.2 Clinical Director*

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

- Assess the clinical need for the proposed new interventional procedure
- Assess whether it will support the objectives of NHS Lothian either through service delivery, teaching and training, or research
- Clinical Directors* (with nursing and other leads where relevant) should satisfy themselves that the relevant clinicians, including members of the wider clinical team who may be involved in the new procedure, have undertaken relevant training.
- The Clinical Director* must ensure a clinical audit programme is in place that will capture data on outcomes and adverse effects that will be used to review continued use of the procedure.

5.2.3 Clinical Service Manager/General Manager/Director of Operations

- Assess the request and, if approved by the CMT, develop a business case which details the estimated costs and other resource requirements of introducing the new procedure and confirms their availability.
- Provide support for the submission to the local committee.

5.2.4 Medical Director of Acute Services, Clinical Directors HSCPs and Associate Medical Director REAS

If a new interventional procedure is approved by the relevant local committee, the Medical Director of Acute Services, Clinical Directors HSCPs or Associate Medical Director REAS must:

- 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 5.2.2.
- Include the new interventional procedure in their annual report to the NHS Lothian Board Healthcare Governance Committee along with the proposed arrangements for clinical audit and collection of data on clinical outcomes that will be used to review continued use, or discontinuation, of the procedure.

5.3 Urgent Indications

- The Board Medical Director, Acute Medical Director, Clinical Directors of HSCPs and/or the Associate Medical Director REAS may grant approval for limited use in the circumstances of an unscheduled indication, until a full submission can be considered.
- In rare circumstances where no other treatment options exist, there may be a need to use a new procedure in an emergency. If a clinician has performed a new interventional procedure in such circumstances, they must inform the Acute Medical Director, Clinical Director of the HSCP or Associate Medical Director REAS within 72 hours. Where the procedure has been carried out as an emergency, the clinician should seek approval of the procedure for future use in line with the agreed process.

5.4 Research

When a new interventional procedure forms part of a research study which has been approved by the Research Ethics Committee (REC) and is supported by the Academic and Clinical Central Office for Research and Development (ACCORD), it will come to the service for management approval. If not already in place, approval by the local committee as set out above should be sought prior to Management Approval being granted.

5.5 National Institute for Health and Care Excellence (NICE)

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 (IPP) 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).

Following approval of the new procedure by the local committee, it should be notified to the IPP at the NICE website, unless it is already listed on their website http://www.nice.org.uk/.

When no guidance exists, NICE will collect data under this programme. Clinicians should supply the information requested on every patient undergoing the procedure. NHS Lothian will 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.

6.0 Associated materials

Proposal for approval of a New Interventional Procedure, January 2026

NHS Lothian New Interventional Procedures Flowchart, January 2026

Support for newly-appointed Consultant Surgeons, October 2025

Scottish Government DL(2017)10 Interventional Procedures Programme

NHS Lothian Consent Policy, approved by the Clinical Policy Group, September 2014 [currently under review]

7.0 Evidence base

National Institute for Health and Care Excellence (NICE) (2009) *Interventional Procedures Programme: Process Guide*. N1716. Available at: https://www.nice.org.uk/media/default/about/what-we-do/nice-guidance/nice-interventional-procedures/interventional-procedures-programme-process-guide.pdf (Accessed: 18 December 2025).

National Institute for Health and Care Excellence (NICE) (2007) *Interventional Procedures Programme: Methods Guide*. N1278. Available at: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/The-interventional-procedures-programme-methods-guide.pdf (Accessed: 18 December 2025).

8.0 Stakeholder consultation

This policy has been reviewed by the Medical Director's Group which is chaired by the Executive Medical Director and comprises all Associate Medical Directors, the Acute Medical Director, Clinical Director of the HSCPs and the Associate Medical Director REAS. The policy was also placed on the NHS Lothian Consultation Zone for a period of 4 weeks to give all NHS Lothian staff an opportunity to provide feedback/comment, and an Equality and Children's Rights Impact Assessment was carried out.

9.0 Monitoring and review

The policy will be reviewed and updated every three years. The Executive Medical Director and Deputy Medical Director will review the annual return from each local committee to the Board Healthcare Governance Committee to assess how the policy is working in practice and may decide on an earlier review if required.

New Interventional Procedures

Name	Who	WHO	approved
Robot Assisted Bronchoscopy	Adam Marshall	CTR	**2608**
Hypothermic Oxygenated Perfusion (HOPE) to improve kidney transplant utilisation		Andrew Sut	**2604**
Cadaveric Cartilage	Rohit Gohil	ENT	**2604**
transcatheter tricuspid valve replacement with the Evoque valve	Nick Cruden	Cardiology	**2602**
Flexible endoscopic treatment of a pharyngeal pouch	Julia Gauci	GI Medicine	**2510**
EVH Cardiac Surgery	*Renzo Pessotto/Daisy Ezakadan*	CTR	**2412**
Thumb joint replacement	Patrick Addison	Plastics	2411
Hybrid Thoracoflo device	Orwa Falah	Vascular	2402
Laser ablation service	Jothy Kandasamy	Neursurger	2305
Lateral Orbital decompression	Robert Peden	Ophthalmo	2304
Zenith arch access for centre procedure	Orwa Falah	Vascular	2212
Chait Tube placement	Stephen Glancy/Sue Reddy		2211
Endovascular Arteriovenous Fistula creation (EndoAVF)	Chris Hay	Chris Hay	2207
Fetal Pillows	Emma Doubal	Obstetrics	2210

2021 No new requests - Covid
2020 No new requests - Covid

Hysteroscopic morcellation of uterine polypus lelomyomas (fibroids)	Gynaecol	190813
Percutaneous renal denervation with the *Spyral*™ catheter	Neal Urel	190709
Ex-vivo normothermic machine perfusion for extracorporeal preservation of livers for transplantat	Gabi Onis	190219
Leadless Pacemake Implantation	Dr Neil R Grubb	180110
Ear Reconstruction with HDPPE Implants	Ken Stewart	180110
Mechanical induction of labour:Cook Balloon	Florence Fankam	170411
Chait tube placement	Caroline Whitworth	170214
Minimally Invasive Glaucoma surgery (MIGS)	Pankaj Agarwal	170110
Gallium-68 PET/CT service	Dilip Patel	170110
Opus device - ventricular remodelling	Renzo Pessotto	161102
Ex-situ normothermic perfusion for liver transplantation	Gabriel Oniscu	161011

Ethanol Ablation of thyroid nodules	Ian Nixon	160809
Endobronchial Valve therapy	Kris Skwarski	160614
Mitraclip	David Northridge, Neil Uren, Miles Bechan	160308
Percutaneous physician inserted PD (Peritoneal Dialysis)	Caroline Whitworth	151208
ED resus camera project	Gareth Clegg	150512
Extra-Corporeal Membrane Oxygenation (ECMO-CPR)	Mike Gillies	150512
3D printing	Scott Inglis (James Hollington no longer involve	150414
Diamond Wire during ‘Edinburgh Osteotomy’	Duncan Campbell	150414
Surety Spinal Needles	Alistair Baxter	150314
Airway Balloon Dilation	Eddie Doyle	150210
Nellix	David Lewis/Paul Burns	141100