Interventional Procedures Policy

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Author:	**Associate Medical Director for Access** **Executive Medical Director**
Responsible Lead Executive Director:	**Executive Medical Director**
Endorsing Body:	**Quality Planning & Professional Governance Group**
Governance or Assurance Committee	**Quality Planning & Professional Governance Group**
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Responsible Person	**Associate Medical Director for Access**

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Contributing Authors:	• **M.G. Downey, Associate Medical Director for Access** • **K. Cormack, Director of Quality**
Consultation Process:	**Professional Leads;** • **Acute Division** • **North & South HSCPs** • **Executive Director of NMAHPs** • **Director of AHPs** **Director of Quality** **Head of R & D** **Quality Planning & Professional Governance Group**
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1. INTRODUCTION

NHS Lanarkshire requires assurance that all healthcare practitioners are competent in all clinical activities that they undertake and that they are supported by appropriately trained staff and have agreed resources in place to ensure delivery of safe and effective care to patients.

NHS DL (2017)10, requires that clinicians who are planning to undertake new interventional procedures should seek approval from their organisation's Clinical Governance Committee before doing so. The role of the NHSL Quality Planning & Professional Governance Group is to review, approve, authorise and monitor, proposed new interventional procedures. This can be procedures that are new to the healthcare professional or clinical team and the use of an established procedure where the safety and/or efficacy has been called into question by new information or advice.

These processes ensure that the healthcare professional seeks prior approval using the appropriate governance structures before the procedure is performed. This also applies to procedures used in an emergency.

Procedures may be known to the NICE Interventional Procedures Programme (IPP) and may be subject to Interventional Procedures Guidance (IPG) or Medtech Interventional Briefing (MIB). If not, then the healthcare professional should notify the IPP at the NICE website. This also applies to procedures where the NICE guidance is under review. In such circumstances, NHS boards are required to support the collection of audit and research data, and the healthcare professionals undertaking these procedures must ensure that the necessary data is sent to NICE.

NICE's Interventional Procedures Programme assesses the safety and efficacy of interventional procedures. 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 with responsibility. The process and methods of the Interventional Procedures Programme are designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, with appropriate input from consultees and other stakeholders, including patients, from across the UK.

There is also a requirement for NHS Boards to ensure that all healthcare professionals deliver care within their existing agreed scope of practice and that any significant change that practice, (although it may involve interventional procedures that are already accepted within the Board as having an evidence base), are adopted within an agreed clinical, educational & financial governance framework.

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From time to time, there may be a new interventional procedure or established clinical procedures, the efficacy or safety of which has been called into question by new information or advice and this situation will also require an enhanced governance structure to support patients and staff affected by this and ensure robust data collection to clarify the risks and benefits nationally. A specific example would be the Restricted Use Protocol with measures to ensure high vigilance scrutiny for surgery for stress urinary incontinence and pelvic organ prolapse as outlined in SGHD/CMO (2018)12.

The Associate Medical Director for Access has responsibility for implementing this policy with local monitoring of any new interventions provided by the specialty Clinical Director.

2. AIM, PURPOSE AND OUTCOMES

In order to achieve the outcome as above, NHS Lanarkshire operational managers must be aware of what procedures are undertaken by healthcare providers within their agreed scope of practice and ensure that there are such supporting resources in place and that there is a regular review of any changing needs within the services that they manage.

This policy describes the governance arrangements to support any change to the known scope of practice, whether that change relates to an individual broadening the scope of their current practice within an existing evidence base or wishes to introduce a new interventional procedure to NHS Lanarkshire that may or may not yet have an evidence base.

In so far as possible, all new interventional procedures and techniques that are introduced should be evidence based. This process is overseen by the Quality Planning & Professional Governance Group (QPPGG), reporting into the Healthcare Quality Assurance & Improvement Committee (HQAIC) as the Board's Clinical Governance Committee.

3. SCOPE

3.1 This policy will provide improved evidence based care to patients in NHS Lanarkshire.

The relevant national policy statements are NHS HDL (2004)04 and NHS DL (2017)10 which are referenced throughout this policy and which are based on the National Institute of Clinical Excellence (NICE) Interventional Procedures Programme.

3.2 This policy is relevant to all healthcare professionals within NHS Lanarkshire: (including but not limited to Consultants, Specialty Doctors & Doctors in Non-Training Grades, Nurses, Midwives & AHP staff and any other healthcare professional who undertake interventional procedures as defined in Section 4).

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This policy applies to the introduction of newly described interventional procedures, to situations where there is a significant change in practice (this will include the introduction of established evidenced based procedures that are new to the operator, the operating team and/or the post procedure care team) and to situation where the efficacy or safety of an established procedure has been called into question. A minor alteration to an established procedure – for example, a small change in the length or site an incision to improve access in an operation would not require authorisation by the QPPGG or necessitate notification to NICE.

The necessity for approval will be judged according to whether the new procedure is likely to have a different safety and/or efficacy profile from the original procedure or requires additional training or other support for staff. In areas of doubt, the Divisional Medical/Nursing Director should be consulted for advice.

NHS Lanarkshire take care to ensure personal information is only accessible to authorised people. We have a legal and contractual duty to keep personal health information secure, and confidential. In order to find out more about current data protection legislation and how we process information, please visit the Data Protection Notice on First Port or ask a member of the Information Governance staff.

4. PRINCIPAL CONTENT

4.1 Definitions

4.1.1 *What is an interventional procedure?*

An interventional ***procedure*** has been defined as "a procedure used for diagnosis or treatment that involves one of the following:

- Making a cut or 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.
- 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 via the mouth.
- Using electromagnetic energy (which includes x-rays, lasers, gamma- rays and ultraviolet light), or ultrasound – for example, using a laser to treat eye problems.

4.1.2 *What is meant by a "new" procedure?*

NHS HDL (2004) 04 specifies that an interventional procedure should be considered "*new*" if either a doctor or other healthcare professional, no longer in a training post, is using it for the first time in their clinical practice or it has not been used in the Health Board before.

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4.1.3 What is meant by experimental?

This would be an intervention that is not 'standard of care' and is not fully accepted as an effective, safe and proven treatment for the condition for which it is being used.

4.2 Introducing a new intervention procedure in NHS Lanarkshire

4.2.1 Key principles

As with any development in clinical practice, the following key principles underpin the introduction of a new interventional procedure:

- All healthcare professionals are personally and professionally accountable for their practice and for ensuring that they have the appropriate training, knowledge and skills to undertake a healthcare procedure that is new to their practice. Training to undertake a new interventional procedure should be to an externally set standard – for example, the appropriate Royal College or Professional Body for the individual performing the procedure; Practitioners will be able to provide evidence of training that has been undertaken.
- Any entirely new interventional procedure should be related to the healthcare practitioners current scope of clinical practice and meet the needs of the service in which they work.
- NHS Lanarkshire has a responsibility to ensure that, in continuing to develop new and innovative practice, safeguards are in place to ensure that patients are not exposed to unacceptable clinical risk.
- An assessment of the rationale for the introduction of the new interventional procedure must be undertaken. This should include an analysis of intended benefits and potential risks to patients, the mitigations that are required and resource implications for NHS Lanarkshire.
- The proposed procedure should have the support of the appropriate Clinical Director and Operational Manager before consideration by the QPPGG.
- Patients must be given sufficient information about the risks, benefits and alternatives to the proposed interventional procedure to enable them to give informed consent. If the interventional procedure is innovative then patients must be told this, why it is being proposed and the experience that the clinician has in undertaking the procedure. Consent must be in line with current legislation and best practice guidance nationally and locally.
- Changes in practice should be formally evaluated and reviewed through audit of clinical outcomes and their annual appraisal process.

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4.2.2 Scope of the Policy

The scope of the policy covers procedures classified as

- New (novel)
- Not new to the NHS but new to the healthcare professional or clinical team
- Experimental
- Where safety or efficacy of an existing procedure has been called into doubt

5. ROLES AND RESPONSIBILITIES

5.1 Individual clinicians;

If a doctor or other healthcare professional is considering the use of a new interventional procedure which he/she has not undertaken before they should:

- Determine if there is existing NICE/SIGN guidance for the proposed interventional procedure. If there is existing guidance, then the proposal should comply with this guidance. Healthcare professionals are expected to take guidance fully into account when exercising their clinical judgement. Published guidance does not however override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient.

- Advise and seek support from their Clinical Director and Operational Manager.

- Provide information on the intended new interventional procedure including the rationale for the development, intended benefits, potential risks, resource implications, information that will be provided to patients and consent procedure, training requirements and methodology to audit clinical outcomes. A proforma has been developed to assist the process of seeking approval from the QPPGG (see Appendix 2).

- Provide information on how the clinician will be trained and assessed as competent in the new interventional procedure including information on the external standards for training that apply.

- If the interventional procedure is approved by the QPPGG then the clinician must collect and report outcome data on all patients who undergo the procedure.

- If an interventional procedure for which there is **no** existing NICE/SIGN guidance is approved by the QPPGG, NICE will require submission of data on the procedure via the National Interventional Procedures Programme. Clinicians should supply the information requested on every patient undergoing the procedure. The collection of data on patients will be governed by the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 2018).

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- Report any adverse events via the NHSL Datix system in accordance with the NHSL reporting policy.

5.2 CD/CME/Specialty Leads and responsible General Managers

If a doctor or other healthcare professional advises that they are considering the use of a new interventional procedure which he/she has not undertaken before, the Clinical Director and Operational Manager should:
Review the information provided by the clinician about the proposed new interventional procedure and:

- Assess if the proposal complies with NICE/SIGN guidance where it exists for the procedure in question.

- Assess the requirement for the proposed procedure and whether it is in accordance with the Strategic and Operational objectives of NHS Lanarkshire.

- Assess any resource implications both within the unit and in other units, if the procedure will have impact on other services – for example diagnostic or imaging services.

If the CD/ leads and responsible General Managers support the proposed new interventional procedure, the proposal should be completed and forwarded to the Divisional Medical/Nurse Directors for support prior to consideration by the QPPGG.
If the Clinical Director and Operational Manager do not support the proposed new interventional procedure, then the clinician concerned should receive formal written feedback outlining the reason for the decision.
If the new interventional procedure is subsequently approved the Clinical Director and Operational Manager must ensure that the healthcare professional has put an audit programme in place to obtain information on clinical outcomes, to continually review the procedure and to obtain information on any adverse outcomes.
A database of approved new interventional procedures and clinicians who have been trained and assessed as competent to undertake them will be maintained by the local specialty performing the procedure and the Divisional Medical Nursing/ Directors informed of any additional clinicians undertaking the procedure.

5.3 Divisional AHP/Nursing/Medical Directors

The Medical/ Nursing Divisional Directors will receive completed proposals for new interventional procedures. They will establish if any additional information is required prior to consideration by the QPPGG.

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Once agreed the proposals for a new interventional procedure will be presented by the Lead Clinician or the Divisional Medical/ Nursing Directors to the QPPG Working Group for consideration.
A register of new interventional procedures submitted for approval to QPPGG detailing the outcome will be established and maintained for each new procedure by the specialty.
A register of approved interventional procedures detailing the clinicians trained and assessed as competent to undertake the procedure will be maintained at service level.
There will be a regular review of patient outcomes and any adverse events at service level which should be reported into the Medical/ Nursing Divisional Directors. An update, including this information will be submitted to QPPGG after 3, 6 and 12 months of performing the procedure. The monitoring form is in appendix 3.

5.4 Quality Planning & Professional Governance Group & Working Group

The Associate Director for Access will establish and chair a New Interventional Procedure Review (NIPR)Group with appropriate representation to provide expertise in relation to the procedure being reviewed. This group will provide recommendations regarding the approval of the procedure to QPPGG. The New Interventional Procedure Review Group will have agreed Terms of Reference with flexible bespoke membership at the discretion of the Associate Director for Access. This may include interested clinicians, specialty and sub-specialist knowledge, senior operational management and representation and other staff groups likely to be impacted.

This group have the authority to approve those requests that relate to procedures already supported by NICE guidance and therefore not requiring any external notification.
If NICE/SIGN have produced guidance on the proposed procedure, the NIPR Group should consider whether the proposed use of the procedure complies with the guidance. If it does, the Group will make a decision whether or not the proposed procedure should be recommended for approval. This decision will be based on the overall benefits and risks to patients, the resource and training implications and the alignment with the strategic and operational objectives for NHS Lanarkshire. The QPPGG will be advised of all proposals whether or not the Working Group has recommended approval. Applicants who have submitted a proposal that has been declined will be notified of the details of the decision making and may submit an appeal directly to the Chair of the QPPGG.

If NICE/SIGN have not produced guidance on the proposed procedure the NIPR Group should only submit proposals for recommendation by QPPGG if;

- The clinician has met externally set standards of training.
- All patients offered the procedure will be made aware of the special status of the procedure and the lack of experience of its use. This will be done as part of the consent process and should be clearly documented.

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The NIPR Group will review and approve associated patient information and must be 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.

If the Working Group recommends the approval of a new interventional procedure for which no NICE guidance exists, NICE will collect data under the New Interventional Procedures Programme and therefore must be notified by the Board. NHS Lanarkshire will support the collection of this data by the healthcare professional to enable the NHS to have access more speedily to guidance on the procedure's efficacy and safety. The only exception to the above process, is where 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.

The Chair of the QPPGG should notify the procedure to the Interventional Procedures Programme at the NICE website unless it is already listed there.

The QPPGG will ensure via the Quality Directorate that a database of submissions and outcomes is maintained.

A flow chart to summarise the approval process for new interventional procedures is attached as Appendix 1.

5.5 The use of a new interventional procedure in a clinical emergency

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 to prevent a patient being at serious risk. If a clinician has performed a new procedure in such circumstances they must inform, their immediate professional lead and appropriate Divisional AHP, Nursing / Medical Directors within 72 hours. The appropriate Divisional Medical/ Nursing Directors will notify the QPPGG.

5.6 Procedures introduced as part of a Research Study

NHS Lanarkshire is a research-active Board. As such, it encourages its staff to engage in high-quality **approved research*** *(as defined below)* for the benefit of our patients, staff, our organization and the NHS as a whole.

Research across the UK is subject to a high degree of scrutiny, including via Sponsors, research funders and NHS Research Ethics Committees (NHS RECs). This scrutiny helps ensure that **approved research** adheres to a set of fifteen core principles** for the conduct of health research in the UK, the first of which is that "…*the safety and well-being of the individual prevail over the interests of science and society*…".

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In line with nationally-agreed research governance arrangements - developed under the auspices of NHS Research Scotland (NRS) and the Scottish Government Chief Scientist Office (CSO) - all relevant national reviews are completed prior to a local review by NHS Lanarkshire's R&D Department that confirms that services have the capacity to conduct the study activities; thereafter local R&D Management Approval is issued to enable the research to proceed.

This Interventional Procedures Policy recognizes the existing national and local governance arrangements that apply specifically to **approved research** - including research involving novel interventions, clinical trials of new medicines and, in regards this policy, *new interventional procedures*. With very limited exceptions, as noted below, it does not seek to impose additional reporting or review arrangements for formal **approved research**, beyond the existing research governance and assurance arrangements previously described.

The exception is where research studies involve new interventional procedures in **high vigilance** areas, or other highly unusual circumstances, as may arise or be notified to the Board from time to time, or identified via the national or local R&D governance reviews of studies. These are expected to be exceptional and rare events – previous examples include:

- research involving transvaginal mesh implants that were notified as '**high vigilance**' by the Scottish Government Chief Medical Officer in their letter (SGHD/CMO(2018)12) to Boards, addressing '*Interventions to Treat Stress Urinary Incontinence and Pelvic Organ Prolapse*'
- research requiring unusual or onerous new governance arrangements, such as studies involving treatments derived from human cells / tissue – these would require NHS Lanarkshire to seek a Human Tissue Authority (HTA) license, and to develop the governance infrastructure to monitor compliance; it would unlikely that studies such as these could be supported

If such circumstances arise, the Board's R&D Committee will discuss the proposed activity in the first instance. If the R&D Committee's view is that a project could potentially proceed in NHS Lanarkshire, formal QPPGG approval would be sought before moving forward.

The system for recording, investigating and managing adverse events is a core aspect in formal research and is designed to promote and improve patient safety. An adverse event (AE) is an untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device or intervention.

There are set arrangements, defined in legislation and national guidance, for safety reporting for research studies (including *Medicines for Human Use (Clinical Trials) Regulations / Medical Devices Regulations 2002 (SI 2002 No 618) / GCP / NHS Health Research Authority / NHS Ethics*).

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These include clear definitions of different categories of adverse incident; examples include: Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Reactions (ARs), Suspected Serious Device Effect (SADEs), Suspected Unexpected Serious Adverse Reactions (SUSARs). There are mandated procedures for recording such adverse events, and for reporting them as appropriate to the research Sponsor, NHS Ethics or MHRA as appropriate.

Approved research conducted within NHS Lanarkshire complies with the relevant guidance related to safety and adverse event reporting, including in relation to adverse events associated with research that involves interventional procedures.

This policy does not require that adverse event reporting, defined within regulations and approved research protocols, is duplicated unnecessarily through internal reporting.

That does not *preclude* local research teams reporting via the NHS Lanarkshire Datix reporting system any adverse incidents that fall out with an approved research protocol's adverse event reporting arrangements.

For the avoidance of doubt, where an interventional procedure is being assessed within the context of a formal research study, the use of that procedure out with the research study / protocol should only occur after approval from the QPPGG using the procedures outlined above.

* The UK Policy Framework for Health and Social Care Research provides the following definition '***research***': "*…the attempt to derive generalisable or transferable…new knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations*…" The UK Data Protection Act 2018 defines '***approved***' as follows: "*…medical research carried out by a person who has approval to carry out that research from a NHS Research Ethics Committee (**NHS REC**)…**or** a research institution…"* [N.B. – '***research institution***' is further defined to include UK Universities]

****https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/**

5.7 Rollout of approved procedures

Once a procedure has been approved by the QPPGG, additional staff who have been trained and assessed as competent may undertake the procedure. Individual clinicians wishing to undertake the procedure will provide the appropriate Medical/ Nursing Divisional Directors with the evidence of their training and competence. A record will be maintained by the clinical service detailing the names of clinicians approved to undertake the procedure.

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6. RESOURCE IMPLICATIONS

Departments will require to complete the associated documentation and keep a record of approved procedures / individuals.

QPPGG will maintain a register of all agreed procedures.

7. COMMUNICATION PLAN

The Policy will be distributed to all healthcare professionals via the professional leadership structures for Medical staff and NMAHPs in NHS Lanarkshire.

8. QUALITY IMPROVEMENT – MONITORING AND REVIEW

QPPGG will be responsible for monitoring and review. See appendix 3 for monitoring form.

9. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire's EQIA √

11. REFERENCES

1. NHS Lanarkshire Generic Fitness to Practice Framework.
2. NHS DL(2017)10; https://www.sehd.scot.nhs.uk/dl/DL(2017)10.pdf
3. NHS HDL (2004) 04; https://www.scot.nhs.uk/sehd/mels/HDL2004_04.pdf
4. National Institute for Health and Clinical Excellence: Interventional Procedures https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/Interventional-procedures-programme-process-guide.pdf
5. SGHD/CMO (2018)12. https://www.sehd.scot.nhs.uk/cmo/CMO(2018)12.pd

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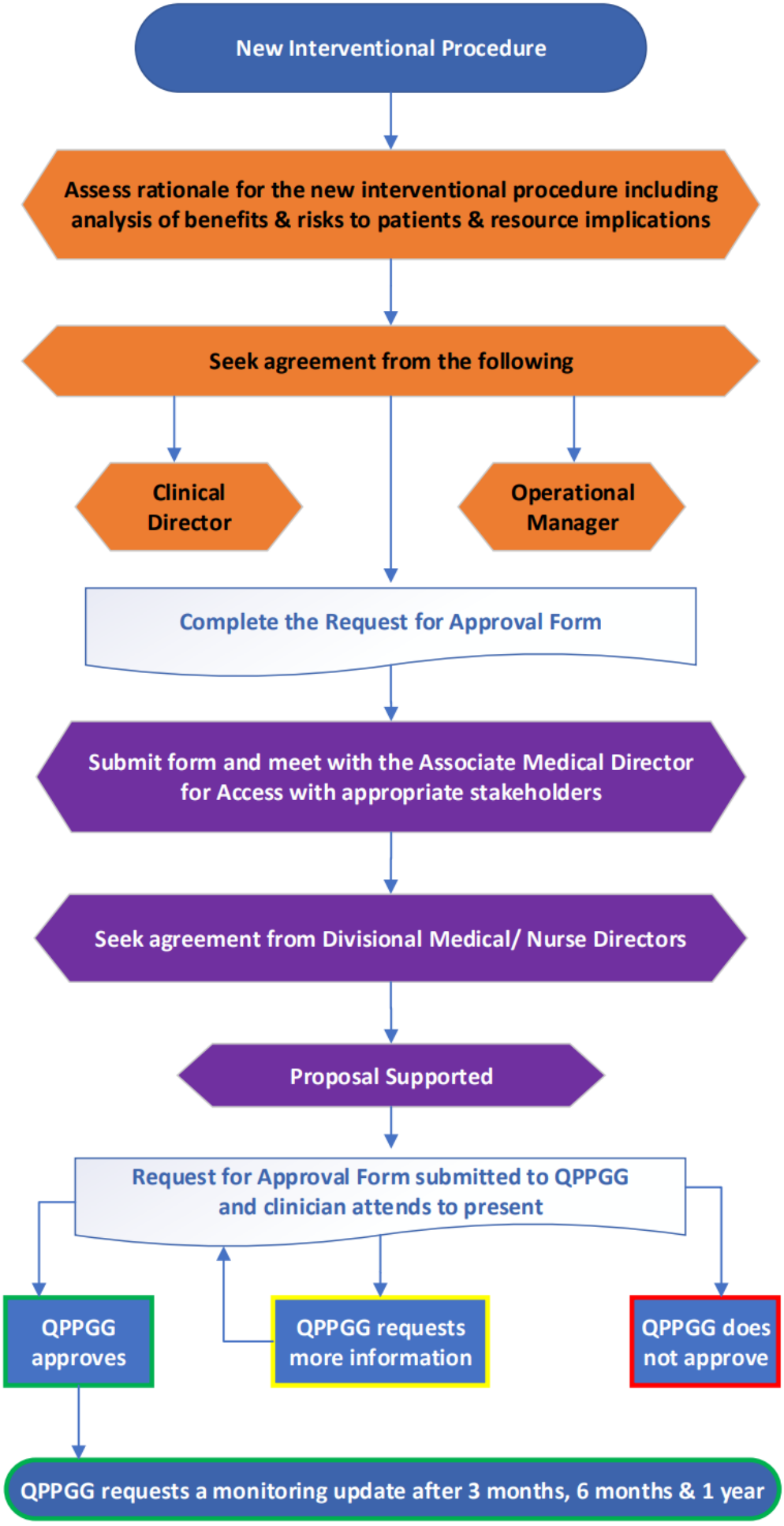
APPENDIX 1


New Interventional Procedure
Assess rationale for the new interventional procedure including analysis of benefits & risks to patients & resource implications
Seek agreement from the following
Clinical Director
Operational Manager
Complete the Request for Approval Form
Submit form and meet with the Associate Medical Director for Access with appropriate stakeholders
Seek agreement from Divisional Medical/ Nurse Directors
Proposal Supported
Request for Approval Form submitted to QPPGG and clinician attends to present
QPPGG approves
QPPGG requests more information
QPPGG does not approve
QPPGG requests a monitoring update after 3 months, 6 months & 1 year

APPENDIX 2

REQUEST FOR APPROVAL TO UNDERTAKE A NEW INTERVENTIONAL PROCEDURE

To be completed by clinician in consultation with Professional Lead and Operational Manager

SECTION 1 Details of the Clinician making the application	
Name	
Job Title	
Base	

SECTION 2 Details of new interventional procedure / technique
Brief description of new interventional procedure / technique* *please enclose a copy of the written information that will be included for patients

Details of evidence base:		
Is there NICE guidance for the procedure? (please tick)	Yes	No
If yes, does the proposal comply with the guidance?	Yes	No
If no, please provide details below:		

Details of any actual or potential risks to patients or staff, including infection control, health and safety:

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Has a risk assessment been completed? (please tick)	Yes	No
Details of benefits:		
Details of patient information and consent process:		
Details of the Clinician who will undertake the procedure / technique		
Name:		
Job Title:		
Please provide details of the approved training programme / evidence that the clinician has been assessed as competent to undertake the procedure / technique:		
Details of arrangements for audit / monitoring:		
Signature of the applying clinician:		
Date of application:		
SECTION 3. Resources / Impact Assessment		
Summary details of any recurrent and non-recurrent costs *(please append detailed costings)*		
Non recurrent:		
Recurrent:		
Source of funding:		
Are there any other resource or service implications? (please tick) *Include impact on staffing or other clinical services and staff groups e.g. Primary Care, Theatre Services, Imaging Services.*	Yes	No
If yes, please provide details below or append:		

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SECTION 4. Professional Lead or Operational Manager supporting the application			
Name:			
Job Title:			
Base:			
Proposal supported (please tick)		Yes	No
If No, please give the reasons below and provide written feedback to the clinician making the application:			
Divisional Medical/Nurse/AHP Director			
Proposal supported (please tick)		Yes	No
If no, please give reasons below:			
Chair of Quality Planning & Professional Governance Group (QPPGG)			
Decision to recommend for approval (please tick)	Yes	No	Requires QPPGG approval
If no, please provide reasons below:			
Signature:		Date:	
QPPGG where required: approval confirmed (please tick)		Yes	No
If there is no existing NICE guidance for the procedure / technique, add the date notified to NICE		Date NICE notified:	
Signature:		Date:	

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APPENDIX 3

MONITORING NEW INTERVENTIONAL PROCEDURE UPDATE TEMPLATE

To be completed by clinician in consultation with Professional Lead and Operational Manager

SECTION 1 Details of the New Interventional Procedure						
Procedure						
Specialty						
Lead Clinician						
Date started						
Stage of update *Please tick*	**3 months**		**6 months**		**12 months**	

SECTION 2 Describe the training implemented of new interventional procedure

SECTION 3 Describe the number of new interventional procedures completed

SECTION 4 Describe any issues or adverse events experienced during this time

SECTION 5 Describe the patient outcomes of the new interventional procedure

SECTION 6 Describe any other pertinent information QPPGG should be aware of

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