Interventional Procedures Policy

| Author: | Associate Medical Director  
| Executive Medical Director |
| Responsible Lead Executive Director: | Executive Medical Director |
| Endorsing Body: | Quality Planning & Professional Governance Committee |
| Governance or Assurance Committee | Quality Planning & Professional Governance Committee |
| Implementation Date: | 3 January 2019 |
| Version Number: | 1.0 |
| Review Date: | 3 January 2022 |
| Responsible Person | Associate Medical Director |
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Contributing Authors:  Mehrdad Malekian, Associate Medical Director
                      Ans Khan, Associate Medical Director
                      Jane Burns, Medical Director

Consultation Process:

Professional Leads;
- Acute Division
- N & SHSCPs
- Executive Director of NMAHPs
- Director of AHPs

Head of R & D

Quality Planning & Professional Governance Group

Distribution:

All Clinical staff, NHS Lanarkshire

Posted on first port

Change Record:

0.1 initial draft by M Malekian, A Khan

0.2 expanded draft input from J Burns re all healthcare practitioners and referencing revised governance structures

0.3 input from R & D

1.0 Ratified Policy following meeting of Quality Planning & Professional Governance Group 10 December 2018
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. (Ref; NHS Lanarkshire Generic Fitness to Practice Framework).

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. This new procedure would then be notified to the interventional procedure programme at the NICE website, unless it is already listed.

NHS boards are required to support the collection of audit and research data on interventional procedures being reviewed by NICE. This means that it must be made known to NICE, which healthcare professionals are undertaking these procedures and ensure that the necessary data is sent to NICE.

The Safety and efficacy of new interventional procedures in the UK were previously assessed by Safety and Efficacy of Register of 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 NICE’s Interventional Procedures Programme.

NICE’s Interventional Procedures Programme now covers Scotland as well as England and Wales. It 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.

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
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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.

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 (QPPG), 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).

This policy applies to the introduction of newly described interventional procedures but also applies to significant changes 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). 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 QPPG 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.

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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 his or her clinical practice or it has not been used in the Health Board before.

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 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 QPPG.

- 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.

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:
Interventional Procedures

- 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 methodology to audit clinical outcomes. A proforma has been developed to assist the process of seeking approval from the QPPG (see Appendix 1).

- 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 QPPG 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 QPPG, 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).

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

5.2 CD/CME/Speciality 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 QPPG. 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 and the Nursing/Divisional Medical Directors informed of any additional clinicians undertaking the procedure.

5.3 Divisional AHP/Nursing/Medical Directors

The AHP, Nursing/Divisional Medical Directors will, as appropriate, receive completed proposals for new interventional procedures. The AHP, Nursing/Divisional Medical Directors will establish if any additional information is required prior to consideration by the QPPG.

The proposals for a new interventional procedure will be presented by the AHP, Nursing/Divisional Medical Directors to the QPPG Working Group for consideration.

A register of new interventional procedures submitted for approval to the QPPG Working Group detailing the outcome will be established and maintained and submitted to the QPPG twice yearly.

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 and reported into the Divisional Governance structure as requested.

5.4 Quality Planning & Professional Governance Group & Working Group
QPPG will establish a Working Group to provide expert recommendations to QPPG. The Working Group will have agreed Terms of Reference and membership and have the authority to approve those requests that relate to procedures already supported by NICE guidance and therefore not requiring any external notification.

The Working Group will be chaired by the Associate Medical Director for Cancer Services & Diagnostics who will agree bespoke membership from senior leaders in NHS Lanarkshire in order to ensure all relevant expertise is available in relation to individual submissions. This will include professional group, specialty and sub-specialist knowledge, senior operational management and representation and other staff groups likely to be impacted.

If NICE/SIGN have produced guidance on the proposed procedure, the Working Group should consider whether the proposed use of the procedure complies with the guidance. If it does, the Working 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 QPPG 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 QPPG.

If NICE/SIGN have not produced guidance on the proposed procedure the Working Group should only submit proposals for recommendation by QPPG 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.

The Working 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 QPPG should notify the procedure to the Interventional procedures Programme at the NICE website unless it is already listed there.

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

A flow chart summarising the approval process for new interventional procedures is attached as Appendix 2.

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 he/she must inform, their immediate professional lead and appropriate Divisional AHP, Nursing / Medical Directors within 72 hours. The appropriate Divisional AHP, Nursing / Medical Directors will notify the QPPG using the procedures outlined above.

5.6 Procedures introduced as part of a Research Study.

New interventional procedures which form part of a research protocol must be approved by a Research Ethics Committee (REC) and have NHS Lanarkshire R&D approval. Any protocol involving a new interventional procedure must be notified to the QPPG Working Group for information and assurance that this governance is in place. If any adverse incident occurs related to the procedure is being undertaken, it should be reported via the NHS Lanarkshire Datix reporting system as well as under the system for reporting adverse events detailed in trial protocol. Use of the procedure out with the research protocol should only occur after approval from the QPPG using the procedures outlined above. Any research studies that involve new procedures in high vigilance areas require QPPG approval before they can proceed.

5.7 Rollout of approved procedures

Once a procedure has been approved by the QPPG, 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 AHP, Nursing/Divisional Medical Directors with the evidence of their training and competence. A record will be maintained detailing the names of clinicians approved to undertake the procedure.

6. RESOURCE IMPLICATIONS
Interventional Procedures

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

QPPG will be responsible for monitoring and review.

9. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire’s EDIA

10. SUMMARY OF POLICY / FAQs

See attached submission form and algorithm as Appendices 1 & 2

11. REFERENCES

1. NHS Lanarkshire Generic Fitness to Practice Framework.
## Proposal for the introduction of a new interventional procedure or technique

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

<table>
<thead>
<tr>
<th>Section 1: Details of clinician making the application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: ________________________________________________</td>
</tr>
<tr>
<td>Job Title: ______________________________________________</td>
</tr>
<tr>
<td>Operational Base: ________________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section 2: Details of new interventional procedure/technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief description of new interventional procedure/technique*:</td>
</tr>
</tbody>
</table>

*Please enclose a copy of the written information that will be provided for patients

Details of evidence base:

<table>
<thead>
<tr>
<th>Is there NICE guidance for this procedure:</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes, does the proposal comply with the guidance:</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>If No, please give details below:</td>
<td></td>
</tr>
</tbody>
</table>

Details of any actual or potential risks to patients or staff, including infection control, health and...
### Section 3: Resources

<table>
<thead>
<tr>
<th>Has a risk assessment been carried out:</th>
<th>Yes □ No □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of benefits:</td>
<td></td>
</tr>
<tr>
<td>Details of the clinician who will undertake the procedure/technique:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Job Title:</td>
<td></td>
</tr>
<tr>
<td>Please provide details of the approved training programme/evidence that the clinician has been assessed as competent to undertake the procedure/technique:</td>
<td></td>
</tr>
<tr>
<td>Details of arrangements for audit/monitoring:</td>
<td></td>
</tr>
<tr>
<td>Signature of applying clinician:</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>
Summary details of any recurrent and non-recurrent costs *(please append detailed costings)*:-

<table>
<thead>
<tr>
<th>Non Recurrent:</th>
<th>Recurrent:</th>
</tr>
</thead>
<tbody>
<tr>
<td>£ _____________</td>
<td>£ _____________</td>
</tr>
</tbody>
</table>

Source of funding: __________________________________________

Are there any other resource/service implications: Yes □ No □  
*(ensure impact on other clinical services and staff groups especially Primary Care are included)*  
If Yes, please provide details below or append:

---

**Section 4: Professional Lead/Operational Manager supporting the application**

Name: ______________________________________________________

Job Title: ______________________________________________________

Operational Base: _______________________________________________

Proposal supported: 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: Yes □ No □  
If No, please give reasons below:

---

**Chair of the QPPG Working Group**

Decision to recommend for approval: Yes □ No □ Requires QPPG consideration □  
If No, please give reasons below:

Signature: ______________________________ Date: ______________

**QPPG where required**

Approval confirmed: Yes □ No □  
If there is no existing NICE guidance for the procedure – date notified to NICE __/__/__

Signature: ______________________________ Date: ______________
Clinician wishes to use a new interventional procedure*
See definition Section 4 NHSL Policy

Is this a clinical emergency?

Yes

Clinician:
- Proceeds with the procedure
- Notifies Professional Lead & Medical/Nurse Director within 72 hours
- Chair of QPPG notified by the Medical/Nurse Director
- Submits proposal
- Completes/sends Proforma to Divisional Nurse/Medical Director

QPPG Working Group approves

No

Clinician:
- Develops proposal
- Secure support of the Professional Lead and CD/Operational Manager

Clinician + CD/Operational Manager:
- Identifies resources, risks and benefits
- Identifies training/competencies
- Completes/sends Proforma to Divisional Nurse/Medical Director

Proposal submitted with recommendations to the next Working Group or at the discretion of the Chair, escalated to exceptional meeting if required

Clinician:
- Identifies training/competencies
- Completes/sends Proforma to Divisional Nurse/Medical Director

Is there existing NICE guidance and does the proposal comply with this

Yes

QPPG Working Group approves

No

Appeal

QPPG does not approve

QPPG Reviews & notifies NICE

Forward proposal to QPPG Working Group Chair

Appendix 2: Flow chart – New Interventional Procedures