New Clinical Interventional Procedures Policy

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Withdrawn Date:

Unless this copy has been taken directly from the Trust intranet site (Pandora) there is no assurance that this is the most up to date version

This policy supersedes all previous issues
## Version Control

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<th>Author/Reviewer</th>
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<td>28/06/2012</td>
<td>Mrs A Lowery</td>
<td>New Interventional Procedures Committee</td>
<td>25/05/2012</td>
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<td>Head of SafeCare</td>
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New Interventional Procedures Policy

1 Introduction

The introduction of new interventional procedures into clinical practice requires a system of controls which protects patients from procedures being performed by unskilled practitioners. Gateshead Health NHS Foundation Trust is committed to ensuring that any new clinical interventional procedure is properly co-ordinated, safe and works well enough for routine use.

2 Policy scope

This policy applies to any health care practitioner/s planning to undertake a new interventional procedure to the Trust that he / she has not used before, or has only used outside the Trust.

3 Aim of policy

The aim of this policy is to assist clinicians to introduce new interventional procedures by providing a robust standard process for the assessment and approval of new interventional procedures within the Trust.

4 Roles and responsibilities

4.1 **The Chief Executive** is ultimately responsible for clinical governance arrangements throughout the Trust and New Interventional Procedures form part of this. The CEO has delegated this responsibility to the Medical Director and Director of Nursing, Midwifery and Quality.

4.2 **The Medical Director and Director of Nursing, Midwifery and Quality** as leads for clinical governance have delegated responsibility from the Chief Executive for ensuring effective governance arrangements for the introduction of new interventional procedures.

4.3 **The SafeCare Council** is responsible for assessing the implications of any areas of concern or potential risk identified through the new intervention procedures committee that have been escalated for their attention and making decisions on whether any course of action should be taken.

4.4 **The New Interventional Procedures Committee** is responsible for assessing and approving applications for the introduction of New Interventional procedures within the Trust.

4.5 The **Associate Medical Director** has delegated responsibility as the operational lead for the approval of New Interventional Procedures.

4.6 **Central Team** are responsible for final approval of any application to introduce a new interventional procedure made by a third party.

4.7 The **SafeCare Department** are responsible for providing an administrative support function for the New Interventional Procedures Committee as well as providing advice in relation to applications for new interventional procedures.

4.8 **Professional staff** are individually accountable for ensuring they follow the governance processes detailed within this policy in relation to New Interventional Procedures.
5. Definitions

For the purpose of this policy, the term “interventional procedure” refers to a clinical practice that involves one or more of the following:

- 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
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) for example, using a laser to treat eye problems
- An interventional procedure should be considered new if a doctor no longer in a training post is using it for the first time in his/her NHS clinical practice.

NICE (2011) www.nice.org.uk/guidance/ip/index

6. Process

6.0.1 Any healthcare practitioner planning to undertake a new interventional procedure that he/she has not used before, or has only used outside the Trusts or NHS should seek the prior approval of the New Interventional Procedures Committee before doing so.

6.0.2 In rare circumstances, where no other treatment exists there may be the need to use a new procedure in a clinical emergency so as not to place a patient at serious risk. If a doctor has performed a new procedure in such circumstances they must notify the Chair of the New Interventional Procedures Committee within 72 hours. The committee will consider approval of the procedure for future use.

6.0.3 All proposals for introduction of new techniques or procedures will be submitted to the New Interventional Procedures Committee via the SafeCare Department for consideration and approval using the proposal form in Appendix 1. All relevant documentation must be completed before submission to the Committee.

The proposal should include the following information:

- A detailed description of the new technique or procedure
- Which group of patients it will benefit
- Evidence base for procedure
- An assessment by professional peer group within the Trust
- Details of associated risks
- Details of the patient consent process
- A patient information leaflet on the procedure
- Details of training and supervisory arrangements
- Evidence of any external training for the procedure and assessment of competence
- Whether ethical approval is appropriate
- Implications for the multidisciplinary team
- Resource implications
- Arrangements for clinical audit
6.0.4 If the procedure is listed on the NICE website, the Committee will consider whether the proposed use of the procedure complies with the guidance before approving it.

6.0.5 If the procedure is not listed on the NICE website, the Committee should only approve its use if:

- 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. 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 patient may then want to know more about the procedure before deciding whether to go ahead. NICE highlights questions patients may want to know in Consent – procedures for which the benefits and risks are uncertain NICE In Appendix 2

- A patient information leaflet on the procedure is available and have been approved by the Patient Information Review Panel.

- The clinician has met externally set standards of training prior to commencement.

- Indication of risk/benefits and effectiveness is provided.

- Revenue or resource consequences should be identified.

- The Committee are assured that the proposed procedure has a sound evidence base. Current supporting evidence in the form of research papers or guidelines should accompany the proposal form.

- Information on the patient group to be affected by the change should be provided

- A list of those practitioners who are to undertake the procedure is provided

- There are no implications for the wider multidisciplinary team for example medical and nursing staff. Does the wider team have the relevant skills and knowledge to ensure safe care of the patient?

- 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. This should include any requirements identified from the National Confidential Enquiries and compliance with NICE guidelines on consent for procedures for which the benefits and risks are uncertain.

- Any new procedure to be introduced must take cognisance of the requirements of the Human Rights Act 1998

6.0.6 When NICE is collecting data under the Interventional Procedures Programme, doctors should supply the information requested on every patient undergoing an approved procedure. NHS Trusts are encouraged to support this to enable the NHS to have access more speedily to guidance on the procedure’s safety and efficacy. The collection of data from patients will be governed by the Data Protection Act.
6.0.7 Where the new procedure application relates to nursing or midwifery staff undertaking a new procedure that has not previously been undertaken by the nursing or midwifery profession within the Trust discussions will firstly take place at the Nursing and Midwifery Professional Forum, chaired by the Director of Nursing, Midwifery and Quality. Only when this forum has given approval can the application be submitted to the New Interventional Procedures Committee.

6.1. Approval

6.1.1 The New Interventional Procedures Committee will make the final decision as whether to give final endorsement to the introduction of the new interventional procedures from a safety and quality perspective. Approval form will be completed and signed by the Chair of the Interventional Procedure Committee (Appendix 3).

6.1.2 Where the application is made by a third party, The New Interventional Procedures Committee will forward the summary discussion & recommendation and discuss with the Trusts Central Team who will make the final decisions as to whether the procedure can be introduced in the Trust.

6.2 Notification to NICE

6.2.1 If the procedure is not listed on the NICE website, the Medical Director will notify the procedure to NICE via their website for guidance.

6.2.2 A new notification to NICE will initiate the following procedure:
- NICE will prepare a brief overview of the evidence on the procedure’s safety and efficacy and consult its Specialist Advisors
- A NICE advisory committee will decide either to issue guidance on the procedure or to seek more information before doing so
- as part of this process, NICE may commission a systematic review of research on the procedure, or set up a national register to collect data about patients who have been treated with it
- NICE consults publicly on all its guidance and its advisory committee will consider responses to consultation before guidance on any procedure is issued

6.2.3 The only exception to the process is when the procedure is being used only within a protocol approved by the Research Ethics Committee. In this case notification to NICE is not needed.

7 Training

7.1 Provision of clinical audit training

Skills in clinical audit are essential for undertaking clinical audits related to NICE Interventional Procedures Programme. The SafeCare Department will provide clinical audit training that can be accessed by all health care professionals who are responsible for auditing the quality of care they deliver. This will include:
- Clinical audit workshops
- Leaflets, information and resources available on the SafeCare intranet site
- Bespoke training for groups and individuals on request.
7.2 Employment and development of clinical audit staff

The trust will employ a team of suitably skilled clinical audit staff to support its programme of clinical audit activity. The Trust will also ensure that these staff have access to further relevant training in order to maintain and develop their knowledge and skills.

8 Equality and diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we treat members of staff and patients reflects their individual needs and does not discriminate against individuals or groups on the grounds of any protected characteristic in accordance with the Equality Act (2010). An equality analysis has been undertaken as part of the development of this policy.

9 Monitoring compliance with the policy

<table>
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<th>Standard/process/issue</th>
<th>Monitoring and audit</th>
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<tr>
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<td>Method</td>
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<td>An audit of compliance with the process for seeking approval to undertake a new interventional procedure as detailed within this policy will be carried out.</td>
<td>Audit of procedure carried out for each proposed new procedure/technique</td>
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10 Consultation and review

Consultation regarding formulation of this policy has been through the Trust and business unit representation of the Interventional Procedures Committee, Clinical Audit Committee and members of SafeCare Council.

11 Implementation of policy (including raising awareness)

Implementation will be lead by the business unit representation on the Interventional Committee/SafeCare Council.

12 References

NICE (2011) www.nice.org.uk/guidance/ip/index
Appendix 1 New Clinical Procedures/Techniques Proposal Form

New Clinical Procedures/Techniques Proposal Form

| Title of Procedure |

1. Have you checked with NICE if the procedure is in development?
   - Yes □  No □  Please do not continue with this form until checked

2. Is it in development?
   - Yes □  No □  Please do not continue with this form until checked

3. Name and Contact Details
   - Name
   - Phone
   - Position
   - Bleep
   - Specialty
   - Email
   - Department

4. Details of Procedure
   - Please outline key features and how it differs from current practice
5 Which Group of Patients will benefit

Please include information on conditions and numbers

6 Evidence base for Procedure

Is a supporting paper attached? Yes ☐ No ☐

Include evidence relating to need, effectiveness and published guidelines and research where available

7 Assessment by professional peer group within the Trust?

Who

When

Consensus
Risks and Consent

Provide Details of Risks, including quantifications


Provide Details of the Patients consent process for the procedures


Is a patient information leaflet attached, has it been approved by the Patient Information Review Panel?

Yes ☐ No ☐

Implications for multidisciplinary teams

Members of Multi-disciplinary teams will need to understand and agree the reasons for new or changed procedures. How was this obtained?


Please give details of training and supervisory arrangements

Outline training and assessment of competence for lead clinician and other staff

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Can you provided evidence of external training for the procedure

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<th>Yes</th>
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Ethical Approval if appropriate

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<th>Has ethical approval been gained</th>
<th>Yes</th>
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If yes enter ethics number below

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Resource Implications identified

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Clinical Audit

Please give details of when and how you intend to carry out a clinical audit against the interventional procedures including proposed time frame.

Please attach a copy of the audit tool and remember to register this with the SafeCare Department.

Application made by

Signature: ___________________________ Date: ______________

Application supported by business unit Associate Director

Signature: ___________________________ Date: ______________

Application supported by business unit Clinical Director

Signature: ___________________________ Date: ______________

Approved by New Interventional Procedures Committee

Signature: ___________________________ Date: ______________

Procedure was not approved by New Interventional Procedures Committee

Signature: ___________________________ Date: ______________

Reason for non approval:
Contents

Who is this leaflet for?

Consent: your choice

Are the benefits and risks of procedures always clear?

Who decides about these procedures?

How can you find out about these procedures?

What does NICE do to get more answers?
What does this mean for you?

Where can I get more information?
Who is this leaflet for?

This leaflet is for patients offered procedures which NICE has said have uncertain risks and benefits.

Consent: your choice

Before a doctor, a nurse or anyone else looking after your health can treat you, they need your consent. That means they must get your agreement, and you need to understand the likely benefits and possible risks before agreeing. For some surgical operations or similar procedures, no one knows for certain what the results of treatment are going to be, and this may affect your decision about having the procedure. This leaflet is your guide to:

- why doctors don’t have all the answers
- how the NHS deals with procedures for which the benefits and risks are uncertain
- what to think about if you are offered such a procedure.

Procedures are treatments that involve one of the following:
- 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.
- 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.
- Using electromagnetic energy (which includes X-rays, lasers, gamma-rays and ultraviolet light) or ultrasound – for example, using a laser to treat eye problems.

Are the benefits and risks of procedures always clear?

No, they are not. Most of the procedures used in the NHS are not new, and we have learnt how well they work and what risks they have. But some procedures are too new to have all the information we need. We are not yet sure just how much benefit they give and which patients get the most from them. We know the short term results of some procedures, but not the longer-term results. All procedures have side effects and risks, and it may take some time to discover exactly what the problems are and how common they are. As well as new procedures, there may be concerns about the benefits and risks of older procedures – for example, if some people don’t seem to do well after having them.

It may be right to choose a procedure for which the benefits and risks are uncertain if doctors think it is likely to help a patient, and the patient agrees, knowing that the outcomes are uncertain – but we must take special care when we haven’t got all the answers about a procedure.

Who decides about these procedures?

The National Institute for Clinical Excellence (NICE) can help. NICE is part of the NHS, and its role is to provide patients, health professionals and the public with guidance on treatment and care for people using the NHS in England and Wales. As part of its work, NICE looks into new (and sometimes not so new) procedures which have been notified to it and decides whether we know enough about how well they work, and how safe they are, to use them routinely. NICE then gives doctors guidance on what to do. NICE also provides information for the public on each procedure it has looked at. If you would like NICE to look into a new procedure, you can notify it via the website (www.nice.org.uk/ip).
How can you find out about these procedures?

Your doctor should tell you if you are being offered a procedure where NICE thinks there is still uncertainty. You may then want to know more about the procedure before deciding whether to go ahead. You may want to know:

- What does the procedure involve?
- What are the benefits that you may get?
- How good are your chances of getting those benefits?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? And how likely are they?
- What may happen if you don’t have the procedure?

You can put your questions to the doctors and nurses looking after you. You can also get information from NICE and you may want to contact a patients’ organisation or charity concerned with your disease or procedure.

What does NICE do to get more answers?

For some procedures, NICE is collecting information about benefits and risks to get a better idea of how useful they are. If this is happening for a procedure that you are having, you will be asked whether you agree that information on the results of your procedure can be used in this way. The process is totally confidential and no one will reveal the results of individual patients’ procedure. If you do not agree, it will not affect the procedure that you have.

What does this mean for you?

In the end, you choose whether to have the procedure. That is your legal and ethical right. There are special arrangements for people who cannot give their consent, perhaps because they are unconscious or very seriously ill. These arrangements are set out in another leaflet, called Consent – what you have a right to expect: a guide for adults (see the last page for details).

For some operations and similar procedures, it is hard to be certain what the results will be, because the treatments are new. But that does not mean you should not have them. It means that, once you have all the information you would like, you need to decide whether you want to have the procedure even though the risks and benefits are uncertain.

Where can I get more information?

You can find out what NICE has said about the procedures it has looked at by visiting NICE’s website (www.nice.org.uk/ip). The NHS Response Line (telephone 0870 1555 455) will send you copies of NICE’s guidance and Information for the Public, but you will need the reference number of the document, which is available on the website. There is more information on consent to treatment in Consent – what you have a right to expect: a guide for adults. You can get this from the Department of Health website (www.doh.gov.uk/consent) or from the NHS Response Line (telephone 0870 1555 455).

The Welsh Assembly Government has also produced the following information on patient consent:

- Reference Guide for Consent to Examination or Treatment; and
- Good practice in consent implementation guide: consent to examination or treatment

These documents are available on the Assembly’s website at: http://www.wales.gov.uk/subihealth/topicse.htm#A&E
Thank you for your recent application and presentation to the New Interventional Procedures Committee. The members of the Committee are now satisfied that the following governance arrangements are in place:

- Training and supervisory arrangements
- Arrangements for Clinical Audit to be carried out including timeframe in which this will be done
- A process for consent and the provision of patient information which has been produced and approved by the Patient Information Review Panel

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The above procedure has been approved for implementation for use within the defined patient group and under the conditions outlined in the New Procedures Proposal Form

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