The Newcastle upon Tyne Hospitals NHS Foundation Trust

Introduction and Development of New Clinical Interventional Procedures

Version No.: 2.0
Effective From: 7 January 2016
Expiry Date: 7 January 2019
Date Ratified: 15 October 2015
Ratified By: New Interventional Procedures Committee

1 Introduction

1.1 As of 13th November 2003, medical practitioners planning to undertake new interventional procedures need to seek approval from the Trust’s “New Interventions Procedure Committee” before doing so (see HC2003/11).

1.2 This policy lays down the procedures to be followed to comply with the requirements of HC2003/11.

2 Scope

This policy applies to all members of staff and covers the introduction of new clinical procedures into the Trust.

3 Aims

Advances in clinical care can often only be made by allowing the introduction of new techniques. However, patient safety must not be compromised. It is important, therefore, that the Trust has a policy to enable new interventional procedures to be introduced safely and with full communication with patients and staff.

4 Roles and Responsibilities

4.1 New Interventional Procedures Committee (NIPC)

The NIPC will develop and monitor strategies for the introduction of new clinical procedures within the Trust.

The NIPC will provide assurance to the Clinical Governance and Quality Committee that new interventional procedures have undergone a thorough appraisal by an appropriately constituted Committee prior to making recommendations to the Clinical Governance and Quality Committee regarding approval of new interventional procedures for use within the Trust.

4.2 Clinical Governance and Quality Committee

Final approval for the use of new interventional procedures within the Trust will be granted by the Chair of the Clinical Governance and Quality Committee. The Medical Director’s Group is also authorised by exception to grant final approval.
4.3 Clinical Governance and Risk Department

The Clinical Governance and Risk Department will maintain the Trust’s Procedures Register, recording the date of the introduction of the new procedure in the Trust, the arrangements for ongoing audit with the Directorate/Department and the review date for reporting on progress back to the New Interventional Procedures Committee (NIPC).

4.4 Research and Development

Research and Development (R&D) will liaise with the NIPC regarding the development and introduction of new clinical procedures. In particular, R&D should notify the New Interventional Procedure Committee of any new high risk interventional procedure which is submitted to the R&D Committee as part of a trial. The procedure will require approval by the New Interventional Procedure Committee prior to use within the context of a research trial and before being used as standard practice.

5 Definitions

5.1 An interventional procedure is a procedure used for diagnosis or treatment which involves one of the following.

- Making a cut or a hole to gain access to the inside of 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 radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.

5.2 An interventional procedure is considered new if it has not been carried out before in this Trust.

6 The New Interventional Procedures Committee (NIPC)

6.1 The Secretary of the Trust’s New Interventional Procedures Committee will check to see if the new procedure has been notified to the Interventional Procedure Programme at the National Institute for Health and Care Excellence.

6.2 If it is registered, the NIPC will consider whether the proposed use of the procedure complies with the guidance before approving it.

6.3 If the interventional procedure is not already listed under the NICE Interventional Procedure Programme, following approval from the New Interventional Procedures Committee, the applicant will ensure that the procedure is notified to the Interventional Procedures Programme at NICE. The NIPC will prepare an overview of the evidence about the procedure and decide whether to issue guidance or seek better information. NICE will
prepare a brief overview of the evidence on the procedure’s safety and efficacy and consult its Specialist Advisors. 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 response to consultation before guidance on any procedure is issued.

6.4 Where the interventional procedure has been used in an emergency so as not to put a patient at serious risk, i.e. where no other treatment option exists, the medical practitioner must inform the Chair or Deputy Chair of the NIPC within 72 hours of the procedure taking place.

7 Registering a New Procedure within the Trust

7.1 Senior clinicians planning to undertake a new interventional procedure are asked to complete the form at Appendix 1 and send the completed form to the secretary of NIPC by electronic mail.

7.2 The practitioner proposing to undertake the new procedure will also need to provide evidence of training and competency which meets externally set standards. The practitioner will be required to attend to the NIPC meeting to present the application to members present.

7.3 Where NICE guidance is available the applicant should ensure that they have clearly demonstrated that their proposed use of the procedure complies within this guidance.

7.4 If the National Institute of Health and Care Excellence (NICE) has not issued guidance on the procedure the Committee should only approve its use if:

- The clinician has met externally set standards of training.
- 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 NIPC 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.

7.5 Following approval by NIPC the practitioner will notify NICE of unregistered procedures using the electronic facilities on the NICE website (with the support of CGARD).

7.6 Where the Committee considers that more information/evidence is required before a decision can be made; this will be communicated to the practitioner, including details of the next meeting of NIPC. In cases where the committee has identified several key issues, the practitioner will also be required to attend the meeting and represent the application.
7.7 All new interventional procedures ratified by the NIPC will be signed off by the Chair or Deputy Chair, recorded within the committee minutes and on the Trust’s New Procedures Register.

7.8 It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use procedure in a clinical emergency so as not to place a patient at serious risk. If a doctor has performed a new interventional procedure in such circumstances he/she must inform the Chair or Deputy Chair of the NIPC within 72 hours. The Committee will consider approval of the procedure for future use as above.

7.9 When the NICE is collecting data under this Programme, clinicians should supply the information requested on every patient undergoing the procedure. The Trust is encouraged to support this to enable the National Health Service 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.

7.10 The only exception to the above process is when the procedure is being used only within protocol approved by a Joint Research Ethics Committee (JREC). In this case, notification to NICE is not needed, as patients are protected by the JREC’s scrutiny. However, JREC should notify the NIPC when they approve a protocol involving an interventional procedure. Use outside the protocol should only occur after approval from NIPC as set out above.

7.11 If an adverse incident occurs in association with a new interventional procedure, this should be reported to the National Patient Safety Agency through the Trust Incident Reporting system in the normal way.

8 Training

There is no specific training associated with this policy.

9 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.

10 Monitoring and Review of Policy

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
</tr>
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<tbody>
<tr>
<td>The registration process and maintenance of the Procedures Register is compliant with the system outlined in this policy</td>
<td>Audit</td>
</tr>
</tbody>
</table>

11 Consultation and review

This policy has been discussed with the NIPC, Clinical Governance and Quality Committee and the R&D Department.
12 Implementation (including raising awareness)

This policy will be publicised on the Trust intranet and via the Trust Policy Newsletter.

13 References

- Health Service Circular HSC 2003/11
- National Institute of Health and Care Excellence web site

14 Associated Policies

- Consent to Examination and Treatment
- NICE Guidelines Implementation Policy
Appendix 1

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

New Interventional Procedure Registration Form

Notes

What is an Interventional Procedure?
The NICE definition of an interventional procedure is one that is used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy, i.e.

- Making a cut or a hole to gain access to the inside of patient’s body – for example, when carrying out an operation or inserting a tube into a blood vessel. The clinician has met externally set standards of training;
- 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 radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.

If you are not sure whether your procedure is “interventional” please discuss your submission with the Chair / Deputy Chair of the Trust’s New Interventional Procedures Committee (NIPC) before sending in your registration form.

What is a New Interventional Procedure?
An interventional procedure should be considered new if it has not been carried out before in this Trust. This also applies to any new high risk interventional procedure which is performed as part of a trial, including those which have been approved by the Research and Development Committee.

Any person considering use in the Trust of an interventional procedure which has not been performed in the Trust before, should seek the prior approval of the Trust’s New Interventional Procedures Committee. They should state whether the procedure is the subject of National Institute for Health and Care Excellence (NICE) guidance as listed on their website, http://www.nice.org.uk/guidance/published?type=IPG. If it is, the Committee will consider whether the proposed use of the procedure complies with the guidance before approving it.

Where no NICE guidance on the procedure is available the committee will only approve its use if:

- The clinician has met externally set standards of training
- 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 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.

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 as not to place a patient at serious risk. If a clinician has performed a new interventional procedure in such circumstances he/she must inform the Chair or Deputy Chair of the New Interventional Procedures Committee within 72 hours. The Committee will consider approval of the procedure for future use as above.
Senior clinicians planning to undertake a new interventional procedure are asked to complete this form and send the completed form to the secretary of the New Interventional Procedures Committee by electronic mail at least 14 days prior to the next NIPC meeting.

Arrangements will then be made for the request to be discussed at the next meeting of the New Interventional Procedures Committee. It is important that you provide the committee members with adequate information. Where NICE guidance is available you should ensure that you have clearly demonstrated that your proposed use of the procedure complies within this guidance. Where no NICE guidance on the procedure is available, you must demonstrate that you have met standards of training, describe the procedure for obtaining informed consent, and define how you will subject the procedure to clinical audit of outcomes. You should provide a summary of the supporting evidence and provide enough abstracts or papers to support the case.

Applicants will be advised of the committee’s decision / recommendation after the meeting and, where appropriate, when clearance for use has been given under the Newcastle upon Tyne Hospitals NHS Trust’s corporate governance arrangements.

What if no NICE guidance is available?

If no NICE guidance on the procedure is available, following approval from the New Interventional Procedures Committee, the applicant will ensure that the procedure is notified to the Interventional Procedures Programme at NICE.

A new notification to NICE will initiate the following:

- 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 response to consultation before guidance on any procedure is issued.

The only exception to the process of registering with NICE is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). In this case, notification to NICE is not needed, as patients are protected by the REC’s scrutiny. However, RECs will notify the Trust’s New Interventional Procedures Committee when they approve a protocol involving an interventional procedure. Use outside the protocol should only occur after approval from the New Interventional Procedures Committee as set out above.

Patients, managers, commissioners and others can also notify procedures directly to NICE through its website.

Adverse Incidents

If an adverse incident occurs in association with a new interventional procedure, this should be reported to the National Patient Safety Agency through the Trust system in the normal way via the national reporting and learning system for adverse events implemented across the NHS.

**Clinicians should discuss their requests and obtain support from any relevant colleagues and their clinical director and / or other clinicians working in their speciality prior to submitting a request.**
New Interventional Procedure Registration Form

REQUEST MUST BE MADE BY A CONSULTANT OR SENIOR CLINICIAN

Please type

<table>
<thead>
<tr>
<th>Clinician’s Name:</th>
<th>Hospital:</th>
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<th>Position:</th>
<th>Phone:</th>
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<tr>
<th>Department/Directorate</th>
<th>Clinical Director</th>
<th>Directorate Manager</th>
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<th>Procedure Title:</th>
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<table>
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<th>Outline of procedure:</th>
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<tr>
<th>Is the procedure listed on NICE’s Website?</th>
<th>Yes □ No □</th>
</tr>
</thead>
</table>

If Yes, please quote the number and title of the procedure, e.g. IPG789 …:

.......................................................... ..........................................................

(and submit a copy of this guidance electronically with this application).

If No, the lead operator / clinician must register the procedure with NICE once approval has been granted.
<table>
<thead>
<tr>
<th>Please describe the procedure and its benefits for lay people (no more than 50 words):</th>
</tr>
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<tbody>
<tr>
<td>Which patients will benefit:</td>
</tr>
<tr>
<td>Advantages over existing procedures:</td>
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<tr>
<td>Would this procedure replace any established procedure?</td>
</tr>
</tbody>
</table>
Evidence base for procedure:

Training received in the procedure and supervision proposed for its introduction:
Implications for multidisciplinary teams (including training). Include details of disinfection procedures, if needed:

Assessment by profession peer group:

Who:

When:

Consensus:
Risks:

(Have any additional risks for people with protected characteristics been considered? age; disability; gender reassignment; maternity and pregnancy; sex; sexual orientation; race; religion. For descriptions of protected characteristics please refer to the Equality and Diversity pages on the intranet)

Describe consent procedure:

Resources involved including within own directorate and others such as within Laboratory or Diagnostic Services.

<table>
<thead>
<tr>
<th>Number of patients likely to be treated per year in directorate:</th>
<th>Estimated cost:</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>This financial year</td>
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<td></td>
<td>£</td>
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</table>

Comments from Business Development Directorate or Finance Directorate:

If a business case has been prepared involving the use of this product please enclose details with this form.
How will the procedure be subjected to clinical audit and outcomes evaluated?

Is this part of any national clinical audit or registry?

If so, who is the lead contact / sponsoring organisation?

Declaration of Interest
Details of any support (financial or in kind, personal or departmental) or sponsorship (for staff, clinical trials, other research, materials, equipment, etc.) received or likely to be received from manufacturer(s)/supplier(s)/sponsor(s) associated with this procedure within the last/next 12 months. If none state NONE.
Other information you may wish to include (including details of support from Clinical Director and/or Clinical Colleagues):

<table>
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<tr>
<th>Proposed start date:</th>
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<tbody>
<tr>
<td>Signed:</td>
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<td>Signed:</td>
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</tbody>
</table>

Date:
New Interventional Procedures Committee
Response to Application to Register a New Interventional Procedure

Trust Address:……………….

From: ………………….
Date:……………………
To:……………………….

Dear

Re: Title of New Interventional Procedure

Thank you for submitting the above proposal to the New Interventional Procedure Committee for consideration. I am writing to confirm that the decision of the New Interventional Procedures Committee, at its meeting held on (Date).

The Committee agreed / rejected the procedure subject to the following:

• (List of caveats / reason for rejection)

As you may be aware, one of the requirements with new interventions is that “if no NICE guidance on the procedure is available, the lead clinician will ensure that the procedure is notified to the Interventional Procedures Programme at NICE.”

To facilitate this, I have attached the link to enable you to do this http://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-interventional-procedures-guidance/IP-notification-form and I would be grateful if you could confirm when this has been done for our records.

Yours sincerely,

Mr S Stoker
Secretary to New Interventional Procedures Committee

cc. Clinical Director
    Directorate Manager
Developing NICE Interventional Procedures

This is a brief summary of how NICE develops interventional procedures guidance.

1. Procedure notified to NICE.
Although clinicians most frequently notify procedures, anyone can make a notification. NICE assesses whether the notified procedure falls within the scope of the Interventional Procedures programme.

2. Interest registered.
NICE lists all notified interventional procedures on the website. Individuals and organisations can register an interest in any interventional procedure. Consultees will be notified by email when consultation begins, and can submit comments.

3. Overview prepared.
NICE consults at least three specialist advisors and prepares an overview of information about the procedure. An independent advisory committee considers the procedure, (Interventional Procedures Advisory Committee, IPAC).

If IPAC decides to produce guidance, NICE issues a consultation document on the safety and efficacy of the procedure. This is posted on the NICE website for a four-week consultation.

5. Final interventional procedures document produced.
IPAC considers the comments from the consultation, then produces final recommendations for the procedure. This is submitted to NICE for approval.

6. Consultees notified.
Once NICE formally approves the final guideline, consultees are notified. They can request a resolution if they think the guidance is inaccurate or the guidance development process has not been followed.

If there are no resolution requests, NICE issues its guidance to the NHS.
Appendix 4 New Interventional Procedures Committee (NIPC) Process Flow

New Procedure agreed by Clinical Director and Directorate Manager

Practitioner submits application to secretary of NIPC (Appendix 1)

New Procedure checked against current list of NICE IPGs by secretary of NIPC

Application reviewed by NIPC

Approved?

Yes

Approved temporary use signed off by NIPC Chair
Clinician meets external standards of training
All patients made aware of special status of procedure
Consent must be recorded. Audit criteria are clear.
(Appendix 2)

Comments returned to practitioner (Appendix 2)

Update Procedures Register

Follow Guidance

Follow up required?

Yes

No

Audit / Case reviews carried out by Practitioner and results submitted to NIPC Secretary

Satisfactory outcomes?

No

Yes

NIPC approve outcome results and procedure continues

NIPC temporarily suspend use of the Interventional Procedure

Applicant/NIPC informs NICE of new procedure (when procedure is being used within protocol approved by JREC NICE do not need to be informed)

Already in NICE IP Programme?

No
The Newcastle upon Tyne Hospitals NHS Foundation Trust

Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. Assessment Date: 22/10/2015

2. Name of policy / strategy / service:
   Introduction and development of New Clinical Procedures

3. Name and designation of Author:
   Mr S Stoker, Clinical Effectiveness Manager

4. Names & designations of those involved in the impact analysis screening process:
   New interventions Procedure Committee chaired by Professor Nick Reynolds

5. Is this a: Policy x Strategy Strategy Service
   Who is affected: Employees x Service Users Wider Community
   Is this: New Revised x
   Who is affected: Employees x Service Users Wider Community

6. What are the main aims, objectives of the policy, strategy, or service and the intended outcomes? (These can be cut and pasted from your policy)
   Advances in clinical care can often only be made by allowing the introduction of new techniques. However, patient safety must not be compromised. It is important, therefore, that the Trust has a policy to enable new interventional procedures to be introduced safely and with full communication with patients and staff.

7. Does this policy, strategy, or service have any equality implications? Yes [ ] No [x]
   If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:
   Any senior clinician can submit an application for consideration by the New interventional Procedure Committee without regard to any protected characteristic.
8. Summary of evidence related to protected characteristics

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups</th>
<th>Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)</th>
<th>Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race / Ethnic origin (including gypsies and travellers)</td>
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<tr>
<td>Sex (male/ female)</td>
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<tr>
<td>Religion and Belief</td>
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<td>Sexual orientation including lesbian, gay and bisexual people</td>
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<td>Age</td>
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<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section</td>
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<td>Gender Re-assignment</td>
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<td>Marriage and Civil Partnership</td>
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<tr>
<td>Maternity / Pregnancy</td>
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9. Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

    Do you require further engagement?    Yes [ ]   No [x]

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)

    No
PART 2

Name: Steven Stoker

Date of completion: 22/10/2015

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)