Policy on introducing
NEW INTERVENTIONAL PROCEDURES
into routine clinical practice

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Author: Clinical Effectiveness Coordinator (James Osborne)

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DMS URL: http://nww.avon.nhs.uk/dms/download.aspx?did=3918
1 EXECUTIVE SUMMARY

1.1 This policy sets out the Trust’s expectations for good governance in the introduction of new interventional procedures within the Trust.

2 DEFINITIONS

2.1 For the purposes of this policy, the term ‘interventional procedure’ refers to a clinical practice for diagnosis or treatment 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 without cutting into the body - for example, inserted via the mouth
- Using electromagnetic radiation - for example, using a laser to treat eye problems.

3 SCOPE

3.1 The policy applies to interventional procedures offered by the Trust to NHS patients, irrespective of the location or staff involved, or if the procedure has been reviewed by the National Institute for Health and Clinical Excellence (NICE).

A separate fuller policy exists covering all NICE Guidance - see ‘Policy on IMPLEMENTING NICE GUIDANCE within the Trust’

3.2 The policy does not apply to the private practice of Trust staff, where the interventional procedure is offered by an external provider to their private patients.

3.3 The policy does not apply where the interventional procedure is offered to patients within the context of a formal research study.

- In such circumstances, the Trust Research & Development Policy applies, which is available at the following URL:
4 UNDERLYING PRINCIPLES

4.1 The Trust aspires to be a leading centre of clinical excellence with an expectation that innovation in diagnosis and/or treatment is an ever-present cultural norm.

4.2 The Trust must be assured that clinical staff are competent in the activities that they undertake.

4.3 The Trust and its staff have a responsibility to ensure that all new clinical interventional procedures that are introduced into practice are safe and clinically effective, and in particular, in line with and in support of NICE Interventional Procedures requirements. (see also 6.2)

4.4 The key factors to be assessed in determining the clinical effectiveness of new interventional procedures include;

- reducing clinical morbidity and mortality
- increasing functional quality of life
- reducing patient length of hospital stay and overall recovery time
- reducing pain
- reducing adverse risks

4.5 The Trust is required to make best use of limited resources available, i.e. to balance both the clinical and the cost effectiveness of any interventional procedure and resultant overall diagnosis and/or treatment

4.6 Where a new interventional procedure replaces an existing procedure or treatment, the clinical effectiveness of the new procedure must be at least equivalent to the existing procedure or treatment.

5 APPLYING TO INTRODUCE A NEW INTERVENTIONAL PROCEDURE

5.1 The responsibility to inform the Trust and gain agreement before proceeding rests with the applying clinician.

5.2 The applying clinician has a responsibility to discuss their developing application with relevant colleagues and to demonstrate their broad clinical and managerial agreement in support of the application within the sponsoring clinical division.
5.3 The applying clinician must notify the Trust through the submission of a formal application to the Trust Clinical Effectiveness Committee.

- The interactive application form is available online on the Trust Intranet (currently at http://intranet/twg/clinical-effectiveness/new-procedures.htm)
- Submission is online. If technical assistance in completing the form is required, this is available from the Clinical Effectiveness Coordinator

5.4 The key elements of the application are as follows;

- Information about the applicant - name, position, contract status, contact details, sponsoring clinical division
- Information about the procedure - name, brief description, disease, current procedure, patient selection, where else offered
- Outline of the benefits and risks - benefits to patients, benefits to the Trust, benefits to the wider NHS, likelihood of a learning curve, risks to patients, patient information leaflet for informed consent
- Outline of the evidence base - if reviewed by NICE or NHS Centre for Reviews & Dissemination and what they conclude, key peer-reviewed studies
- The key finance implications - likely financial impact, demonstrable divisional manager support, attached business case where appropriate, statement of any conflicts of interest
- Information about relevant specialist training - evidence of accredited training, any initial presence of visiting experts
- Anticipated clinical audit - whether current data is available for comparison, future audit criteria, audit timetable
- Requested start date

5.5 The Clinical Effectiveness Coordinator will act as the named liaison between the Clinical Effectiveness Committee and the applicant.

5.6 The application will be considered at the next available meeting of the Clinical Effectiveness Committee, which typically meets monthly.

5.7 Where a new procedure is being considered within an emergency situation, the clinician is expected to consult with senior colleagues and if possible with
the Medical Director. Following the event, the Chair of the Clinical Effectiveness Committee must be informed within 72 hours, and a formal application considered for future use.

6 REVIEWING A SUBMITTED APPLICATION

6.1 Where NICE have published interventional procedure guidance on the proposed new procedure, the Clinical Effectiveness Committee will reflect their guidance in its decisions;

- When NICE determine that the ‘evidence on safety and efficacy of … is adequate to support the use of the procedure provided that normal arrangements are in place for consent and audit and clinical governance’, the focus of the Committee in reviewing the application will be satisfactory submissions relating to the above caveats, and that the applicant clinician has met externally set standards of training. It is not expected in such circumstances that the Committee will repeat the detailed review of primary evidence, as this has already been conducted by NICE.

- When NICE determine that the ‘evidence on the safety and efficacy of … does not appear adequate to support the routine use of this procedure without special arrangements for consent and for audit or research’, the Committee in reviewing the application will take into account any fresh supporting evidence provided, that there are satisfactory submissions relating to the above caveats, and that the clinician has met externally set standards of training.

- When NICE determine that the ‘evidence on safety and efficacy of … does not appear adequate to support the routine use of this procedure. It is suitable for use only within good-quality research studies approved by a research ethics committee and with explicit patient consent’, the default position of the Committee will be to refuse the application, and to redirect the applicant to considering the procedure within the context of a research study.

6.2 When it is known that NICE are developing guidance on the interventional procedure, the default position of the Clinical Effectiveness Committee will be to defer the application until the guidance is formally published.

- A list of published and ‘in development’ interventional procedure guidance is maintained by NICE at the following URL: http://guidance.nice.org.uk/page.aspx?o=ipsearch

6.3 If the procedure has not been notified to NICE, the Clinical Effectiveness Committee should only approve its use if the following conditions are met;
• Sufficient credible peer-reviewed evidence is provided as to the safety and efficacy of the procedure

• Documentary evidence that the clinician has met externally set standards of training, or that such training has been scheduled

• Patients 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.

• Proposed arrangements for clinical audit are sound and will capture data on clinical outcomes that can be used to review continued use of the procedure. Where possible, a pre-determined standard of acceptable clinical performance should be established, in order to allow the Trust to determine that anticipated clinical endpoints have been achieved.

• Where the submitted evidence is internally contradictory, an option open to the Committee is to refer the procedure for formal consideration by NICE. More information on this process is available at the following URL: http://www.nice.org.uk/page.aspx?o=ts.home

7 THE APPROVAL PROCESS

7.1 The applicant may be asked to attend the meeting of the Clinical Effectiveness Committee in person, in order to answer anticipated detailed questions arising from their application.

7.2 The decision of the Clinical Effectiveness Committee must be formally recorded in the minutes of the Committee

7.3 The decision of the Clinical Effectiveness Committee will be issued to the sponsoring clinical division in writing, signed by the Chair of the Clinical Effectiveness Committee.

7.4 In some circumstances, the approval may be conditional, for example on satisfactory performance as demonstrated by clinical audit.

8 APPEALING THE DECISION

8.1 Where an application is deferred or refused, the Chair of the Clinical Effectiveness Committee will provide a timely explanation in writing to the applicant and the sponsoring clinical division.
8.2 Where an application is deferred or refused, the applicant has the right of appeal and updated resubmission to the Chair of the Clinical Effectiveness Committee, and if further necessary, to the Trust Medical Director. There must be documented support for the appeal by the sponsoring Clinical Divisional Board.

9 ASSURING THE POLICY

9.1 The assurance framework for this policy is summarised in the following table;
### Table summarising the assurance framework for this Policy

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>What</th>
<th>When</th>
<th>Who By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant staff are aware of the need to seek authorisation</td>
<td>Consultant Information Packs on Induction Days and Away Days</td>
<td>Annual</td>
<td>Clinical Effectiveness Coordinator</td>
</tr>
<tr>
<td>Application forms are adequately completed</td>
<td>Submitted applications</td>
<td>Following online submission</td>
<td>Clinical Effectiveness Coordinator</td>
</tr>
<tr>
<td>Application forms are circulated to Clinical Effectiveness Committee</td>
<td>Committee agenda papers / emails</td>
<td>Annual</td>
<td>Clinical Effectiveness Coordinator</td>
</tr>
<tr>
<td>Clinical Effectiveness Committee reviews and decides on applications</td>
<td>Committee minutes</td>
<td>Annual</td>
<td>Clinical Effectiveness Coordinator</td>
</tr>
<tr>
<td>Process for ensuring that agreed clinical audit is scheduled</td>
<td>Registered Clinical Audit Project</td>
<td>Following approval by Clinical Effectiveness Committee</td>
<td>Clinical Lead (Applicant) Speciality Clinical Audit Convenor Speciality Clinical Audit Facilitator</td>
</tr>
<tr>
<td>Clinical audit results demonstrate expected clinical benefits</td>
<td>Speciality clinical audit meeting minutes and audit report</td>
<td>As stipulated in application form, no later than six months following commencement of procedure</td>
<td>Clinical Lead (Applicant) Clinical Effectiveness Coordinator</td>
</tr>
<tr>
<td>Agreed patient information is offered to patients</td>
<td>Documented in patient treatment notes as demonstrated by representative audit</td>
<td>Annual</td>
<td>Clinical Lead (Applicant) Speciality Clinical Audit Facilitator</td>
</tr>
</tbody>
</table>
9.2 A summary of approved procedures will be listed on the Trust Intranet

9.3 The Policy as a whole will be formally reviewed by the Clinical Effectiveness Committee every two years.

10 ROLES AND RESPONSIBILITIES

This section lists the key staff or group roles referred to in this policy, with a brief summary of their relevant responsibilities

10.1 Clinical lead (applicant)
- To seek authorisation from the Trust before introducing new interventional procedures
- To submit an application to the Clinical effectiveness Committee
- To prepare and agree a business case, where advised by the relevant divisional manager
- To develop/adapt an appropriate patient information leaflet
- To fully inform prospective patients of the benefits and risks associated with the procedure, compared to standard treatment, and to record this interaction within patient notes

10.2 Clinical Effectiveness Coordinator
- To liaise with clinical lead applicants to ensure that the submitted application form is fully completed
- To circulate completed applications to the Clinical effectiveness Committee
- To formally refer to NICE any new procedures apparently new to the NHS

10.3 Clinical Effectiveness Committee
- To review received applications carefully, and to make an assessment on the clinical effectiveness of the proposed procedure, taking into account known benefits/risks and proposed arrangements for training/supervision, informed consent, and clinical audit.
- In arriving at a decision, the Committee should take into account any relevant guidance issued by NICE or the NHS Centre for Reviews & Dissemination
- To request additional information from and personal attendance of the Clinical Lead Applicant, where there is uncertainty on any aspect of the proposed procedure

10.4 Clinical Audit Convenor & Facilitator
- To liaise with clinical lead applicants in scheduling appropriate clinical audit into the speciality forward programme
- To ensure that the audit is conducted and results presented locally, with appropriate action plans documented and signed off