The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Trust Operational Policy

Clinical Governance & Quality Department

Introduction of a New Technique or Medical Device

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Royal Liverpool and Broadgreen University Hospitals NHS Trust Policy Website
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Any printed copies must therefore be viewed as “uncontrolled” and as such, may not necessarily contain the latest updates and amendments.

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1.0 Introduction

"New medical technologies can bring many benefits to patients, carers and clinicians. They can improve the quality of life of patients through more efficient and effective treatments; enable patients to remain in their homes rather than being admitted to hospitals or care homes; make remote diagnosis and treatment possible; reduce treatment times; and enable clinicians to treat more patients more effectively."[1]

However it is vital that the introduction of any new technique or medical device takes into consideration not only costs, implication and benefits but also ensures any risks to patients, staff and the Trust are minimised.

This policy provides a framework to assist staff in the formal process of introducing a new technique or medical device into the Trust. As per the November 2003 Health Service Circular The Interventional Procedures Programme (Appendix 4) 'medical practitioners planning to undertake new interventional procedures should seek approval from their NHS Trust's Clinical Governance Committee before doing so.'[2] The Clinical Governance Structure within the Trust includes the Techniques and Medical Devices Group to promote this process.

The remit of the Techniques and Medical Devices (TaMD) group includes independently evaluating the clinical and cost effectiveness of the introduction of a new technique or medical device.

The Trusts Medical Device Management and Decontamination Policy and Procedures document should be referred to in regards to the acquirement and use of any device.

2.0 Objective

The object of this policy is to ensure that there is a formal but objective process for the introduction and monitoring of all new techniques and medical devices, whilst minimising risks to patients, staff and the Trust and ensuring the true costs, implications and benefits are considered.

3.0 Scope of Policy

This policy applies to all staff wishing to introduce a new technique or medical device or a significant modification to an existing technique or medical device.

4.0 Policy

The Techniques and Medical Devices Group was formed following the merger of the New Techniques and Devices group and the Medical Devices Group. This merger is to allow not only a formal process for the introduction of a new technique or medical device but also their continual monitoring and provides support from the Clinical Governance Structure. The Group report formally to the Clinical and Cost Effectiveness Sub-Committee.

A formal application process is in place and must be followed by all staff who wish to introduce a new technique or medical device. An evaluation will be conducted to establish the risks to patients, Trust and staff and ensure that every measure is taken to minimise these risks. Consideration will be given to the training needs of individuals or teams carrying out the procedure or technique, the current evidence base and cost implication.

4.1 Definitions

New Technique or Medical Device

Any technique or medical device that has not been previously used in the Trust is classed as new, regardless of whether it has been used elsewhere.

4.2 When should an application be made to the Techniques and Medical Devices group

- **If it has not previously been used in the Trust but is an established technique and/or device in the UK:**

  A New **Introduction of a New Technique or Medical Device** form needs to be submitted to the Techniques and Medical Devices group and approved before anything can be implemented.

- **If it has not previously been used in the Trust and is not an established technique and/or device:**

  You may require ethics approval, therefore you should seek ethics advice or approval from the Ethics Committee prior to submitting an application to Techniques and Medical Devices.

- **If it has been used previously in the Trust and is established:**

  This is a matter between you and your Directorate. You and your team should have sufficient training to perform the technique safely in respects of the patient, your team and yourself. Your Directorate is responsible for making a decision on costs and funding. Some Directorates will have their own advisory/mentor group to assist you and the Directorate.

4.3 Application Form

An application form (Appendix 3) for the introduction of a new technique or device is available on the Trust's intranet site and must be fully completed. The form has been designed to be as straightforward as possible; this is because in most instances the applicant will already have other supporting documentation that can be submitted with the application form.

The applicant must conduct an investigation as to whether a Medical Device Alert has been published in relation to the proposed medical device. This should be done by searching on the online Cochrane, MHRA, NICE, NPSA

databases which can be accessed as an electronic link within the application form. The Health and Safety Manager can be contacted for support regards Medical Device Alerts.

The completed application form together with the supporting documentation should then be sent to the TaMDg administrator (mailto:TaMDg@rlbuht.nhs.uk), who will ensure it is considered at the next scheduled Techniques and Medical Devices Group meeting.

As minimum, applications will be supported with the following:

- Signatures of Directorate Manager, Directorate Accountant, and Clinical Director. If the applicant is a Clinical Director, then Sub-Specialty and Divisional Medical Director signatures are warranted.
- Possible technique/ device incidents and safety alerts have been researched.
- Training method that the applicant/team will undergo.
- Completed application form to include signed declaration of applicant's interest.
- Articles/summary of current available evidence
- Draft patient information leaflet clearly indicating the technique or medical device is new and what the potential risks and benefits are.
- Completed NICE Suggest A Topic – form (Appendix 5) if the application is in regard to an Interventional Procedure for which guidance has not/is not being published by NICE.

Any applications submitted without the above will be returned to the applicant and will not be discussed until all documents and signatures are received.

4.4 Approval Process

Applications are considered by the Trust's Techniques and Medical Devices Group who meet on a monthly basis, during which a full evaluation of the application is conducted. The financial, resource and training implications will be considered, as well as the benefits, risks, and the safety of patients and staff.

The applicant will be invited to the meeting to ensure that any areas that require further clarification can be discussed. Should further information be required that is not available at the meeting this will be requested from the applicant formally in writing within two weeks. The response will then be considered at the next scheduled meeting.

The applicant may opt to be accompanied by a manufacturer representative to answer questions beyond the applicants knowledge related to a device, however their input will be restricted to a question and answer format, and shall be requested to leave the meeting room when complete.

The applicant will be informed of the group's decision formally within 2 weeks of the Techniques and Medical Devices meeting or once all documentation (including signatures) has been received. Any conditions attached to the approval will be included in the formal letter.

Applications will be logged on the Trust's Clinical Effectiveness database.

4.5 Ongoing Evaluation and Audit

Applicants will be requested to submit a formal evaluation report to the Techniques and Medical Devices Group after a pre-determined number of procedures have been conducted or after a set time period, but no longer than 12 months. This will be stipulated in the approval letter.

4.6 Adverse Incidents

Any incident related to the new technique or medical device must be reported immediately via the Trust electronic incident reporting system to the Risk Manager, stating clearly that it relates to a new technique or medical device. The Risk Manager will notify the group of the incident via the Chair of the group.

4.7 Use of a New Technique or Devise prior to approval by TaMD group

'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.'[2] If this occurs then discussions with the Clinical Director as a means to provide clinical governance should be undertaken, as well as the Medical Director should be informed within 72 hours, via the chairman of the TaMD group. The reasons and processes in regards to the use of the technique and/or device must be provided in writing to the chairman and there must be clear documentation within the clinical notes in regards to its use.

If use of the technique/medical device is intended to be continued then the approval processes indicated within this policy must be followed.

5.0 Roles and Responsibilities

5.1 Applicant

The applicant is responsible for meeting the requirements as set out in this policy and include:

- Ensure an application form is complete and is undertaken in unison with the Directorate Manager and Directorate Accountant, with all relevant signatures (or approval by email) submitted.
- Be available to discuss the application at a Techniques and Medical Devices group meeting.
- To pre-notify the TaMDg administrator if you are to be accompanied by manufacturer representation.
- Inform relevant parties of the introduction of the approved technique or medical device including informing Sterile Services when an order has been placed for any new medical device.
- Ensure the associated patient information leaflet is formally approved by the patient information Forum.
- Provide a completed NICE Suggest A Topic – form (Appendix 5) if applicable and submit it to NICE.

- Ensure any adverse incidents are reported on Datix risk reporting software and to the Chair of TaMDg within 48 hours
- Investigate whether a Medical Device Alert has been published on the device.
- Ensure evaluation and monitoring of the technique or device is carried out
- Provide the Techniques and Medical Devices group with an update as specified in the approval letter.
- All conditions noted in the approval letter are adhered to.
- Ensure patients are informed they may be contacted at a later date for monitoring purposes.

Applications made by a Clinical Director/Lead must be approved by the Divisional Medical Director and Sub-Specialty Lead.

5.2 Directorate Accountant

The Directorate accountant is responsible for ensuring the true costs associated with the introduction of a new technique or medical device are clearly identified and the costs can be met.

5.3 Directorate Manager

The Directorate Manager will be advised of the new technique and/or medical device by the applicant and will be responsible for ensuring the training and cost implications have been fully considered and discussed and that a Business Case is applicable. They will also ensure all successful applications are monitored through the Directorate Performance Review. Directorate Management is responsible for investigating incidents related to a new technique or medical device.

5.4 Clinical Director/Lead

The Clinical Director will be advised of the new technique and/or device by the applicant and will be responsible for evaluating the clinical advantages and safety to patients. Applications made by a Clinical Director/Lead must be signed by the Divisional Medical Director.

5.5 Techniques and Medical Devices Group

The TaMD group will be responsible for:

- Independently evaluating the clinical and cost effectiveness of all applications.
- Prepare a letter to the applicant with a copy to the relevant Clinical Director, Directorate Manager and Divisional Medical Director with their recommendations.
- If a Clinical Audit is required the approval letter should also be copied to the Divisional Effectiveness Facilitator.
- Agree a timescale for the evaluation of the new technique or medical device
- Be responsible for the monitoring of new techniques or medical devices.

5.6 Chair of the Techniques and Medical Devices Group

The Chair of the TaMD group will be responsible for ratifying all applications approved by the Group.

5.7 Divisional Medical Director

The Divisional Medical Director is responsible for ensuring that all new techniques or medical devices introduced in their division fit in to their clinical governance performance review. They will also be responsible for the approval of an application made by a Clinical Director/Lead.

5.8 Effectiveness Lead

The Clinical and Cost Effectiveness Coordinator will be responsible for:

- Ensuring administrative is provided to support to the Techniques and Medical Devices Group.
- Ensuring the Divisional Medical Director is provided with a copy of all relevant applications.
- Support applicants in completing their applications where appropriate.
- Informing NICE of any application that is in regards to an Interventional Procedure for which guidance has not/is not being published by NICE (unless the applicant wishes to do so themselves).

6.0 Associated documentation and references

- [1] Health Service Circular HSC 2003/011 November 2003: The Interventional Procedures Programme, Working with the National Institute for Clinical Excellence to promote safe clinical innovation
- [2] The Use of New Medical Technologies within the NHS, Fifth Report of
- Session 2004–05 Volume I, House of Commons Health Committee
- Strategy for the Implementation and Monitoring of National Institute of
- Health and Clinical Excellence (NICE) Guidance
- Medical Device Management and Decontamination
- Policy and Procedures document
- Incident Reporting Policy
- Consent to Examination and Treatment Policy
- Patient Information Policy

7.0 Training & Resources

The training and skills required by those who would carry out a new technique or use a new medical device should be clearly identified within the application form.

8.0 Monitoring and Audit

New Technique or Medical Device

Evaluating the results of the outcome of a new technique or device is vital. The Techniques and Medical Devices Group will determine and agree with the applicant the numbers of procedures conducted, or the amount of time, but no longer than 12 months before they would require a report on the outcomes.

The applicant or a person nominated by the Directorate Manager in the applicant's absence will be responsible for producing and presenting the report to the Techniques and Medical Devices group, this will include the evaluation form and financial proforma to support this.

Introducing a New Technique or Medical Device policy

The Effectiveness Lead will provide quarterly reports to the Techniques and Medical Devices group on submitted applications and their status, results of audits or evaluations and any concerns identified through this process.

9.0 Equality and Diversity

Trust is committed to an environment that promotes equality and embraces diversity in its performance as an employer and service provider. It will adhere to legal and performance requirements and will mainstream equality and diversity principles through its policies, procedures and processes. This policy should be implemented with due regard to this commitment.

To ensure that the implementation of this policy does not have an adverse impact in response to the requirements of the Race Relations (Amendment Act) the Disability Discrimination Act 2005, and the Equality Act 2006 this policy has been screened for relevance during the policy development process and a full impact assessment conducted where necessary prior to consultation. The Trust will take remedial action when necessary to address any unexpected or unwarranted disparities and monitor practice to ensure that this policy is fairly implemented.

This policy and procedure can be made available in alternative formats on request including large print, Braille, moon, audio, and different languages. To arrange this please refer to the Trust translation and interpretation policy in the first instance.

The Trust will endeavour to make reasonable adjustments to accommodate any employee/patient with particular equality and diversity requirements in implementing this policy and procedure. This may include accessibility of meeting/appointment venues, providing translation, arranging an interpreter to attend appointments/meetings, extending policy timeframes to enable translation to be undertaken, or assistance with formulating any written statements.

9.1 Recording and Monitoring of Equality & Diversity

The Trust understands the business case for equality and diversity and will make sure that this is translated into practice. Accordingly, all policies and

procedures will be monitored to ensure their effectiveness.

Monitoring information will be collated, analysed and published on an annual basis as part of our Single Equality and Human Rights scheme. The monitoring will cover all strands of equality legislation and will meet statutory employment duties under race, gender and disability. Where adverse impact is identified through the monitoring process the Trust will investigate and take corrective action to mitigate and prevent any negative impact.

The information collected for monitoring and reporting purposes will be treated as confidential and it will not be used for any other purpose.

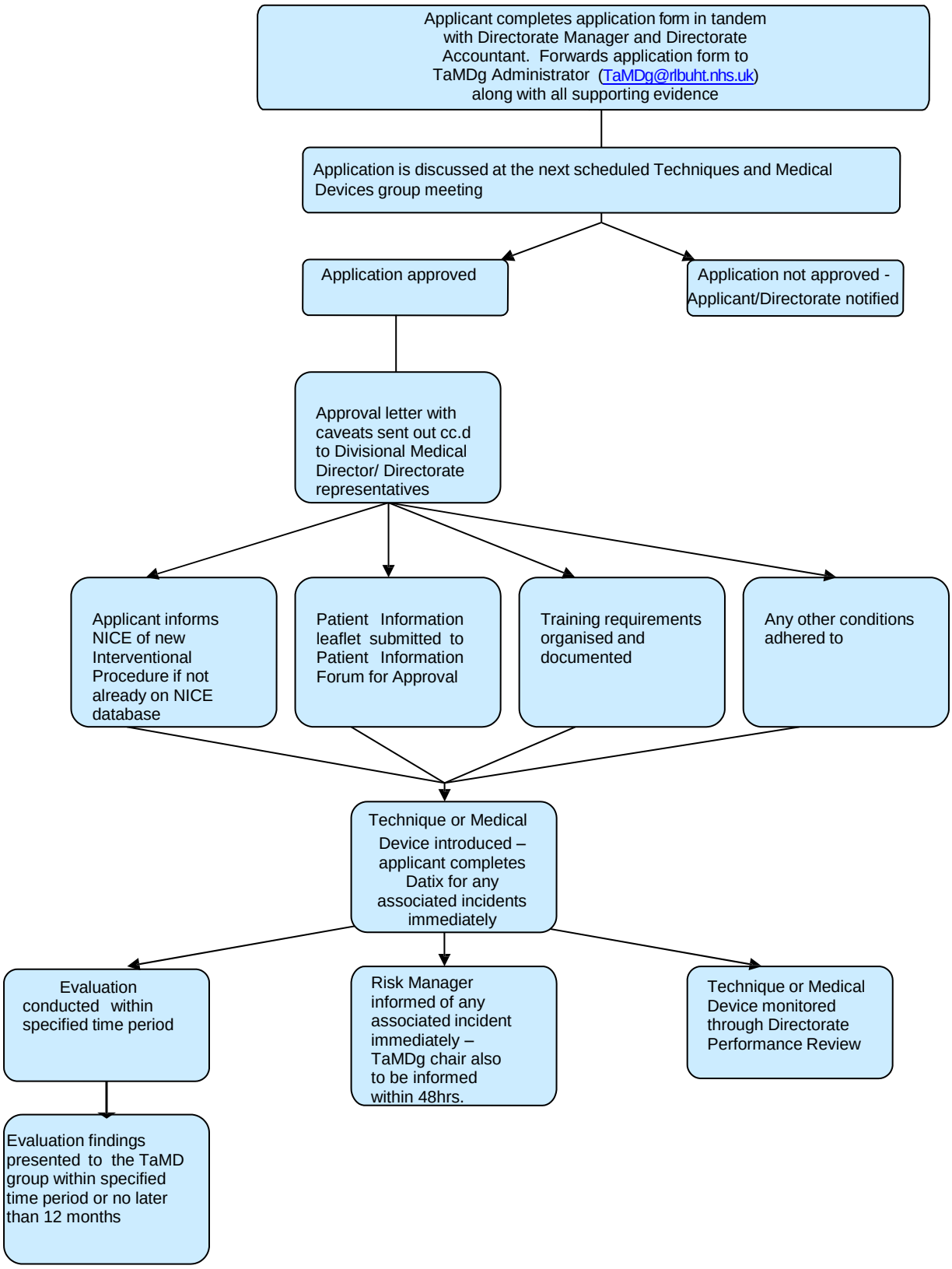
Appendix 1

Glossary of Terms used within Policy

New Technique or Medical Device

Any technique or medical device that has not been previously used in the Trust is classed as new, regardless of whether it has been used elsewhere.

Appendix 2
Process Flow



Appendix 3
Techniques and Medical Devices Application Form

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Techniques and Medical Devices Group (TaMDg)
Application form for the Introduction of a New Technique or Medical Device
Please return completed forms to **TaMDg@rlbuht.nhs.uk**

To be completed by the applicant in conjunction with the Directorate Manager

Name of Clinical Lead:	**Internal Contact Number (& Mobile)**
Name of Directorate Manager:	**Internal Contact Number (& Mobile)**
Directorate:	
Name/Title of New Technique/Medical Device:	
Summary of clinical topic to be addressed by new Technique/Medical Device:	

Your application will need to be supported by the following documentation. Please cross the relevant box to indicate that the specific document/s has/have been attached to your application form:

	Sufficient detail about the new technique or device with reference to the advantages and the risks to the patient.
	Current evidence available on research previously conducted – *to be reviewed by the applicant and attached* Questions for Evaluation of Studies .
	Possible technique/ device incidents and safety alerts have been researched using the following databases and resource tools. Cochrane, MHRA, NICE, NPSA. ***((Click on the respective title to access)***
	Please indicate if a (Patient Information Form) PIF is applicable to your application Yes/No Draft Patient Information Leaflet (as per Trust template). All information should include the risks (with percentages or likelihood of risks occurring) benefits, alternatives and effects of no treatment.
	Please liaise and obtain from the manufacturer any device or safety alerts related to the

	application.
	CE mark/product license. ***Please provide number*** [ ]
	Please provide NICE Interventional Procedure Guidance (IPG) no. …….. or tick to confirm NICE have been informed of this if an IPG has not been published (as per **New Techniques and Medical Devices policy** (see Appendix 3.)

Training method of applicant/team (Please cross relevant box(s):			
	Audio visual		Training demonstration/seminar
	Trained by expert/ Centre of Excellence		Mentored by expert

Declaration of Competing Interests[1]

A competing interest exists when professional judgment concerning a primary interest (e.g. this application) may be influenced by a secondary interest (such as financial gain, involvement in trials or personal rivalry)

This section should be filled in by both the applicant and the Clinical Director

1. Have you, in the past five years, accepted the following from an organisation that may in any way gain or lose financially from the result of your application:

	Applicant	**Clinical Director**
Reimbursement for attending a symposium?	Yes/No	Yes/No
A fee for speaking?	Yes/No	Yes/No
A fee for organising education?	Yes/No	Yes/No
Funds for research?	Yes/No	Yes/No
Funds for a member of staff?	Yes/No	Yes/No
Fees for consulting?	Yes/No	Yes/No

2. Have you, in the past five years, been employed by an organisation that may in any way gain or lose financially from the results of your application?

	Yes/No	Yes/No

3. Do you hold any stocks or shares in an organisation that may, in any way, gain or lose financially from the results of your application?

	Yes/No	Yes/No

4. Have you acted as an expert witness on the subject of your application?

	Yes/No	Yes/No

5. Do you have any other competing financial interests?

	Yes/No	Yes/No

If yes, to question 5 please specify here:

If you have answered "yes" to any of the above 5 questions, we consider that you may have a competing interest, which, in the spirit of openness, should be declared. Please draft a statement to be submitted with your application below. It might, **for example**, read:

- *Competing interest: RS has been reimbursed by Shangri La Products, the manufacturer of Elysium, for attending several conferences; TD has been paid by*

[1] The declaration of interest section is taken from the International Committee of Medical Journal Editors' Unified Competing Interest form currently being trialed by the British Medical Journal.

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Shangri La Products for running educational programmes and has her research registrar paid for by the company; JS has shares in the company.

We are restricting ourselves to asking directly about competing financial interests, but you may want to disclose another sort of competing interest that would embarrass you if it became generally known after consideration of your application. The following list gives some examples.

- A close relationship with, or a strong antipathy to, a person whose interests may be affected by your application.
- An academic link or rivalry with somebody whose interests may be affected by your application.
- Membership of a political party or special interest group whose interests may be affected by your application.

If you want to declare such a competing interest then please add it to your statement.
Statement of Declaration of Interest:

Name of Applicant..... …… Signature …… Date …….

Name of Clinical Director …… Signature …… Date …….

Directorate Support	
All signatures must be obtained before submission. (Signatories are encouraged to attach additional recommendations/comments)	
Directorate Accountant – Please cross appropriate box(s):	
	Funding has been fully identified for all additional costs
	Funding has been identified to cover expected additional costs
	No funding identified but additional costs expected
	No additional costs expected (e.g. cost neutral)
	Additional financial implications/recommendations attached
Procedure	
How many procedures and over what period of time are to be undertaken?	
How many procedures are currently carried out? [ ]	
Will the new technique/ device impact the Trust's activity volume? Yes/No – If yes, how?	
Please quote the current OPCS (Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures)/ ID Code [ ]	
Does the new technique or device change the coding? If yes, what is the impact on the Healthcare Resource Group (HRG) tariff?	
Capital Costs	

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Please provide details of any items that will require sterilisation e.g. containers / trays.	
Please provide details of capital costs of any new equipment.	
What would the maintenance arrangements be? Are there any additional costs? Yes/No. If yes, please provide details.	
Impact on Revenue Costs	
Details of current consumables (price (£) and volume)	£: Volume:
Details of future consumables (price (£) and volume)	£: Volume:
Are additional consumables required? Yes/No If Yes – please specify.	
Is there an additional impact on theatre time? Yes/No If Yes – please specify.	
If additional theatre sessions are required please provide details.	
Please detail any other impact on staff time or numbers.	
Please provide details of any associated costs.	
Summary of financial impact (To be completed by the Divisional or Directorate Accountant).	
Signature of Directorate Accountant ……. Date ……..	
Clinical Lead (Applicant)	
☐ Additional recommendations/comments attached. **Signature of Clinical Lead. ……. Date ……..…**	
Directorate Manager	

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☐	Additional recommendations/comments attached. **Signature of Directorate Manager…….. Date ……**
Clinical Director	
☐	Additional recommendations/comments attached. **Signature of Clinical Director …….. ……. Date ……** ***(If the applicant is the Clinical Director the signature of the Divisional Associate Medical Director is required)***

New Technique/Device Evaluation Form	
Name of Lead Clinician:	
Designation:	**Directorate:**
Name/Title of New Technique/Medical Device:	
Feedback process ***to be agreed at TaMDg meeting*** Written report/presentation to TaMDg *delete as appropriate After [ ] number of procedures or After [ ] months Feedback to include: • Total number of procedures • Complications • Method of training • Financial analysis (cost benefit) Please also refer to the TaMDg Mandatory Update Form. TaMDg Mandatory Update Form	
Clinical Audit Required: Yes/No - If yes, please complete audit proforma (include link)	
Anticipated date initial evaluation findings to be reported to the Techniques and Medical Devices group. ***To be agreed in conjunction with TaMDg on approval of application.***	
Applicant Signature	

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Signature: …… Date ……
Chair of T&MD group Signature
Signature: …… ……..Date……..
Department Reference no. (Leave blank)

Application Outcome					
	Approved		Not Approved		Approved subject to changes
Recommendations:					
Signed by Chair of T&MD group …….. ……Date……					

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Health Service Circular

Series Number:	**HSC 2003/011**
Issue Date:	**13 November 2003**
Review Date:	**12 November 2005**
Category:	**Clinical Effectiveness**
Status:	**Action** *sets out a specific action on the part of the recipient with a deadline where appropriate*

The Interventional Procedures Programme

Working with the National Institute for Clinical Excellence to promote safe clinical innovation

For action by:	NHS Trusts - Chief Executives
For information to:	NHS Trusts – Chairman Primary Care Trusts - Chief Executives Medical Schools – Deans Medical Directors Directors of Nursing National Care Standards Commission National Patient Safety Agency Commission for Health Improvement

Further details from: Paul Woods
Department of Health
Room 415
Wellington House
133/155 Waterloo Road
London
SE1 8UG
020 7972 4811
paul.woods@doh.gsi.gov.uk

Additional copies of this document can be
obtained from: Department of Health
PO Box 777
London
SE1 6XH
Fax 01623 724524

It is also available on the Department of Health
web site at
http:/www.doh.gov.uk/publications/coinh.html

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The Interventional Procedures Programme

Working with the National Institute for Clinical Excellence to promote safe clinical innovation

1. From 13 November 2003, medical practitioners planning to undertake new interventional procedures (see definition on page 4) should seek approval from their NHS Trust's Clinical Governance Committee before doing so. The Chair of the Clinical Governance Committee should notify the procedure to the Interventional Procedures Programme at the National Institute for Clinical Excellence (NICE) unless it is already listed there. In a case where the procedure has to be used in an emergency (see below) the procedure should be notified to the Clinical Governance Committee within 72 hours.

2. The only exception to the process is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC).

Purpose of the Programme

3. NICE's Interventional Procedures Programme assesses the safety and efficacy of new 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 responsibly.

How the programme works

4. Medical practitioners intending to carry out a new interventional procedure should seek the approval of their NHS Trust's Clinical Governance Committee. If the procedure is not listed on NICE's website (www.nice.org.uk/ip), the Chair of the Committee should notify the procedure to NICE via the website. A new notification 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.

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

What the NHS should do

6. The success of the Interventional Procedures Programme is dependent on appropriate engagement from the NHS.

7. Any doctor considering use in the NHS of a new interventional procedure which he/she has not used before, or only used outside the NHS, should seek the prior approval of their NHS Trust's Clinical Governance Committee. If the procedure is the subject of NICE guidance, the Committee should consider whether the proposed use of the procedure complies with the guidance before approving it.

8. If no NICE guidance on the procedure is available, the Committee

should only approve its use if:

- the doctor 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.

9. The Committee should also take account of the Clinical Negligence Scheme for
Trusts standard 5.2.6.

10. 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 doctor has performed a new interventional procedure in such circumstances he/she must inform the Clinical Governance Committee within 72 hours. The Committee will consider approval of the procedure for future use as above.

11. When NICE is collecting data under this Programme, doctors should supply the information requested on every patient undergoing the 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.

12. The only exception to the above process 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 should notify Trust Clinical Governance Committees when they approve a protocol involving an

interventional procedure. Use outside the protocol should only occur after approval from the Clinical Governance Committee as set out above.

13. If an adverse incident occurs in association with a new interventional procedure, this should be reported to the National Patient Safety Agency in the normal way via the national reporting and learning system for adverse events to be implemented across the NHS in 2003.

14. CHI 's review teams assess how well clinical governance is working in Trusts bymaking enquiries about each of the seven components of clinical governance at corporate and directorate levels and in clinical teams. This involves collecting information systematically about review issues and will include how Trusts' Clinical Governance Committees introduce new interventional procedures.

Definitions

15. An *interventional procedure* is one used for diagnosis or treatment that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy.

16. 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 or her NHS clinical practice.

Associated Documentation

17. Further information can be found on the NICE website www.nice.org.uk/ip and the Programme can be contacted via ip@nice.nhs.uk

This Circular has been issued by:

Professor Aidan Halligan
Deputy Chief Medical Officer

Appendix 5

Suggest a topic – form

Your name: _____

Your email address: _____

Your postal address (if you do not have an email address): _____

Date: _____

Your role / perspective:
(please select ONE option which best describes your role)

☐ Member of the public
☐ Patient
☐ Health professional
☐ Healthcare industry
☐ Voluntary or community group / organization
☐ Other

Your location

☐ England
☐ Wales
☐ Scotland
☐ Northern Ireland
☐ Elsewhere in Europe
☐ United States
☐ Other

Are you making a suggestion on behalf of an organisation or as an individual?

☐ Individual ☐ Organisation

Please state the name of the organisation: _____

Appendix 5

Suggest a topic – form

1. Suggestion: Please briefly describe your suggestion for us (maximum 50 words)

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2. What is the specific illness / condition / behaviour, or public health issue?

Examples:

- □ Cystic fibrosis
- □ Cancer-related anaemia
- □ Smoking cessation
- □ Physical activity
- □ Depression
- □ Early death through health inequalities
- □ Uptake of childhood vaccinations

(maximum 40 words)

Appendix 5

Suggest a topic – form

3. Are there any specific groups of patients, or the public, that your suggestion applies to?

_____

(maximum 40 words)

Examples:

□ Age specific group, such as older people
□ A specific gender (male or female)
□ Patients who have already had a heart attack
□ Patients for whom other therapies have not been successful
□ Patients with advanced disease
□ People at risk of this illness / condition, for example a genetic condition

4. Are there any specific interventions or aspects of care you are suggesting?

_____

(maximum 40 words)

Examples:

□ Prevention / health promotion
□ Testing / investigation
□ Diagnosis
□ Drug development
□ Other treatment or therapy

Appendix 5

Suggest a topic – form

5. Equity

Are there any issues about health inequality that you would like to highlight in your suggestion?

_____

Notes:

Health inequality describes differences in health, or in access to health services, between different population groups (according to socio-economic status, geographical area, age, sexual orientation, disability, gender, ethnic group, religion or belief)

DATA PROTECTION

The information you submit via this website will be retained and used by the National Institute for Health and Clinical Excellence and the Institute's advisers for the purpose of topic selection and related work in accordance with the Data Protection Act 1998. The information may be kept on an Institute database for the purposes of future reference, research and statistical analysis by the Institute and other approved third parties. Please do not name or identify individuals in your comments. The Institute may wish to contact you and if we do it will be by email or by post.

*☐ By submitting your data on this website you are confirming that you have read and understood this statement and accept that personal information, including sensitive data, sent to us will be retained and used for the purposes and in the manner specified above

Please email this form to or send any other feedback to: topicsuggestion@nice.org.uk or post to:

Rachel Hatton, Topic Selection Coordinator, National Institute for Health and Clinical Excellence, Level 1A, City Tower

Appendix 5

Suggest a topic – form

Equality monitoring form for topic suggestors

This section of the form will be used for monitoring purposes only. NICE is committed to promoting equality and eliminating unlawful discrimination. We seek to achieve diversity in the membership of our advisory bodies by ensuring that no applicant receives less favourable treatment on grounds of (but not limited to) sex, race, colour, religion, marital status, sexuality, age, ethnic origin, or disability, or is placed at a disadvantage by conditions or requirements that cannot be shown to be justifiable

☐ Under 18
☐ 18–35
☐ 36–50
☐ 51–65
☐ Over 65
☐ I do not wish to disclose this

☐ Male
☐ Female
☐ I do not wish to disclose this

I would describe my ethnic origin as:

Asian or Asian British
- ☐ Bangladeshi
- ☐ Indian
- ☐ Pakistani
- ☐ Any other Asian background

Black or Black British
- ☐ African
- ☐ Caribbean
- ☐ Any other Black background

Mixed
- ☐ White & Asian
- ☐ White & Black African
- ☐ White & Black Caribbean
- ☐ Any other mixed background

White
- ☐ British
- ☐ Irish
- ☐ Any other White background

Other Ethnic Group
- ☐ Chinese
- ☐ Any other ethnic group
- ☐ I do not wish to disclose this

Please select the option which best describes your sexuality

- ☐ Lesbian
- ☐ Gay
- ☐ Bisexual
- ☐ Heterosexual
- ☐ I do not wish to disclose this

Please indicate your religion or belief

- ☐ Atheism
- ☐ Buddhism
- ☐ Christianity
- ☐ Hinduism
- ☐ Islam
- ☐ Jainism
- ☐ Judaism
- ☐ Sikhism
- ☐ Other
- ☐ I do not wish to disclose this

Do you consider yourself to have a disability?

- ☐ Yes
- ☐ No
- ☐ I do not wish to disclose this

Appendix (6)

Maintain a record of the documents history or reviews and key changes made, including versions and dates)

Appendix (6)

Version	Date	Comments	Author
1.0	15.1.04		P Carter
2.0	1/10/06	Circulated to members of the CCEG for comments	P Thorpe
3	12/02/10	Policy reviewed and agreed by Techniques and Medical Devices group	J Machin
4	09/07/2012	Minor changes made to reflect updated process and policy in new Trust format	S Byrne

Review Process Prior to Ratification:

Name of Group/Department/Committee	Date
Clinical & Cost Effectiveness Group	02/07/10
Techniques and Medical Devices Group	13/07/12