GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number**: UHB 274 **Version Number: 1** **Date of Next Review:**16/06/2018

New Procedures Procedure

Introduction and Aim

This procedure describes the process to implement the New Procedures Policy.

The aim is to ensure any new procedures introduced in to clinical practice within Cardiff and Vale University Health Board (UHB) are done so safely and within the current economic and commissioning frameworks.

Objectives

- To ensure compliance with requirements laid down by the National Institute for Health and Care Excellence (NICE) in the Interventional Procedures (IP) Programme.
- To ensure that all new clinical techniques and procedures that are introduced into clinical practice are safe and effective.
- To ensure competence, consent, and reporting arrangements for current practice wherever there are issues of patient safety.
- To assist staff with identifying their roles and responsibilities in ensuring that appropriate actions are taken by individuals, groups and committees with regard to ensuring patient safety, clinical effectiveness and best outcome when introducing new procedures.
- To appropriately assess options and manage demand for NHS services in line with the *All Wales Prioritisation Framework*

Scope

This procedure applies to all of our clinical staff in all locations including those with honorary contracts.

Equality Impact Assessment	This is covered by the Equality Impact Assessment the New Procedures Policy. The Equality Impact Assessment completed for the policy found there to be potential for positive and negative impacts depending on the new procedure being implemented – each will have its own EqIA.
Documents to read alongside this	1. National Institute for Health and Care Excellence (NICE) Interventional Procedures (IP) Programme Methods Guide.

Procedure / references	http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/The-interventional-procedures-programme-methods-guide.pdf 2. National Institute for Health and Care Excellence (NICE) Interventional Procedures (IP) Programme Process Guide. http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/Interventional-procedures-programme-process-guide.pdf 3. Health Service Circular (HSC2003/011) - Department of Health http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4064925.pdf 3. New Procedures Policy 4. Interventions not normally undertaken (INNU) list part 1 (http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/165527) 5. All Wales Policy for Individual Patient Funding Requests (http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/220685) 6. All Wales Prioritisation Framework - December 2011 (http://www2.nphs.wales.nhs.uk:8080/HealthTopicLeads.nsf/85c50756737f79ac80256f2700534ea3/c997185d64441b3980257bb80049f48d/$FILE/Prioritisation%20Framework_Final%2021-12-11.pdf 7. UHB 138 Incident, hazard and near miss reporting policy and procedure http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/198125 8. UHB 100 Consent to examination or treatment policy http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/186989
Approved by	Quality, Safety and Experience Committee
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Quality and Safety Improvement Manager

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	16/06/2015	23/10/2015	New Procedure

Contents Page

1.0 INTRODUCTION

This procedure is primarily aimed at trained clinical staff with professional autonomy to modify practice. It is equally pertinent to all staff with any clinical contact where harm might follow the unregulated development, or adoption of new techniques or procedures.

The procedure is potentially wide reaching and is intended to include clinical competence in all circumstances in addition to new procedures and NICE procedures.

The Department of Health issued a Health Service Circular (HSC2003/011) explaining that medical practitioners planning to undertake new interventional procedures (except in emergencies or when the procedure is being used only within a protocol approved by a Research Ethics Committee) must now seek approval according to the policy – and ideally from a relevant Committee before doing so.

Decisions relating to safety need to be made in the context of the natural history of the condition being treated or investigated, and the alternative treatments available.

Health Boards and Trusts have been made responsible for the prudent introduction of clinical innovations. This local procedure is in line with requirements laid down by the National Institute for Health and Care Excellence (NICE) in the Interventional Procedures (IP) Programme.

'The IP Programme assesses the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately.

By reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the efficacy and safety of interventions, the Programme enables clinical innovation to be conducted responsibly. The Programme gauges the extent of risks and benefits and makes recommendations in terms of their implications'. [1 (p5)]

The UHB is expected to have a system in place to manage innovation. This system should recognise the need for training and ensure that it is made available, reflect the need for openness and informed consent from the patient, ensure the reporting of adverse events, and facilitate the collection of audit data.

2.0 DEFINITION OF A NEW PROCEDURE

NICE define an interventional procedure as: 'A procedure used for diagnosis or treatment that involves incision, puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy.' [1 (p39)]

NICE guidance stipulates that to fall within the remit of the Interventional Procedure (IP) Programme, a notified interventional procedure must:

- Involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy
- Be available within the NHS or be about to be used for the first time in the NHS, outside formal research
- Be either not yet generally considered standard clinical practice, or a standard clinical procedure, the safety or efficacy of which has been called into question by new information.

NICE considers an interventional procedure to be “new” if a fully trained clinician is considering the use of a procedure/technique for the first time in the NHS outside Research Ethics Committee approved protocol. Performing an established procedure using a new device would not usually fall within the remit of the policy/this procedure unless the use of the new device appears to alter the safety and efficacy of the procedure.

In practice these principles apply to any circumstance in which any healthcare professional proposes to carry out a clinical procedure with which they are unfamiliar and which, by its nature, may expose the patient to risk.

The term clinician includes any health practitioner engaged in the care of a patient.

3. ADHERANCE TO NICE GUIDANCE

3.1 Nice Guidance

The UHB must be assured that all practitioners are competent in all the activities that they undertake. As part of this requirement, there is a responsibility to ensure that all new clinical techniques and procedures that are introduced into clinical practice are safe and effective, and in particular, in line with, and in support of NICE Interventional Procedures requirements and NICE Medical Technologies requirements.

Local decision makers should not regard the lack of NICE Guidance, or guidance that the procedure is of uncertain safety and efficacy as a reason to automatically resist the use of the procedure, but they should satisfy themselves that local use of the procedure fulfils all the conditions on use that NICE stipulates.

All new or personally developed clinical procedures, major modifications of established practice, procedures new to the UHB and procedures with NICE Guidance must be agreed before introduction.

This procedure is not intended to affect minor incremental change in clinical practice and, over-reporting to the UHB (and NICE) is encouraged. It does not apply to the introduction of new drugs, which are dealt with separately by the Medicines Management Group.

3.2 Notification to NICE

Procedures should be notified to NICE if:

- They are entirely novel, with an unknown or uncertain efficacy and/or safety profile; or
- They are a variation of an established procedure which is likely to have a different efficacy and/or safety profile from that of the established procedure.

The responsibility to inform the UHB and gain agreement before proceeding rests with the individual clinician. The individual clinician has a responsibility to inform the UHB and NICE by submission of the attached form (Appendix 1) of any procedure which might fall into this category.

4.0 COMMISSIONING

In order to manage demand for NHS services the *All Wales Prioritisation Framework* was introduced in December 2011 and provides a clear, rational approach for all Health Boards and the Welsh Health Specialised Services to use when assessing options for resource allocation.

If an intervention does not form part of the routine schedule of UHB services, and is also not listed in the interventions not normally undertaken (INNU) list part 1 (which may include new and experimental treatments yet to be assessed) (add http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/165527) requests for it to be undertaken can also be made using the process set out in the *All Wales Policy for Individual Patient Funding Requests* (http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/220685) in clinically exceptional circumstances.

The policy for INNU should be adhered to where the evidence of clinical benefit in relation to harm and/or cost effectiveness is limited to such a degree that undertaking them may be unjustifiable. They are either not normally available on the NHS in Wales, or are available within specified criteria.

5.0 ROLES AND RESPONSIBILITES

Refer to the Interventions Procedures Process Guide. NICE 2009 [2]

5.1 Executive Lead / Corporate responsibility

The Medical Director has delegated accountability for ensuring all clinical techniques and procedures that are introduced into clinical practice are safe and effective and in particular, in line with and in support of NICE Interventional Procedures and NICE Medical Technologies guidance requirements.

The Medical Director is responsible for the performance management of the process for the introduction of new interventional procedures through reviewing and authorising or rejecting new procedures.

For procedures with “cautionary” NICE guidance or no NICE guidance, approval of requests will be granted by the Quality, Safety and Experience

Committee on behalf of the Chief Executive, taking advice and guidance from appropriate sources including clinicians, Directorate/Departments, Risk Management Teams, Clinical Governance and outside sources, as necessary.

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.

A documented meeting using the New Procedures Application form will be held by the Medical Director or their nominated deputy to discuss and record the training/competency record of the clinician, the information given to patients, a sample consent form, an agreement to report clinical incidents, and arrangements for notification of procedures performed/audit undertaken.

The Medical Director or their nominated deputy must sign the appropriate part of Section 9 of the New Procedures Application form (appendix 1) to authorise the Clinician(s) to carry out the new procedure.

The Medical Director or their nominated deputy must send the completed application form to the Clinical Audit Department where it will be filed and recorded.

A central database of new procedures will be maintained and outcome monitoring will be performed on behalf of the Medical Director by the Clinical Audit Department.

New procedures with revenue consequences will only be introduced after business planning approval.

5.2 Role of the Clinician/Practitioner

5.2.1 Gaining approval

All clinicians considering performing a new interventional procedure in the NHS which he/she has not done before, or only outside the NHS, should complete sections 1-8 of the New Procedures Application form (appendix 1) and then send the application to the Clinical Director to start the authorisation process.

5.2.2 Governance/risk management

Clinicians must only perform procedures for which they can produce evidence of training/expertise.

New procedures must be registered with the UHB Clinical Audit Department using the New Procedures Application form.

Recommendations are made for clinicians to use the procedure only with special arrangements for consent and/or audit and/or research. It is also stipulated that the clinical governance/patient safety lead should be notified.

This recommendation is often made when the procedure is considered to be emerging practice in the NHS.[1 (p30)]

'When making judgements about safety, both the magnitude (seriousness) and frequency of adverse events need to be considered. A low risk of very damaging complications is generally considered to be a more significant safety issue than a high risk of minor complications. The most important consideration is that patients (or their parents or carers, when appropriate) should be informed and should understand the risks when offered the procedure. This always means telling them the known risks, but in addition it may mean telling them that there is uncertainty about the frequency (risk) of complications – in particular uncommon and serious ones' [1 (p22)]

A measuring and monitoring system to assess the effect of processes on clinical outcomes must be in place such as prospective or retrospective clinical audit or other appropriate balanced system of measures.

Incident reports must be completed for any untoward events as per the UHB incident reporting policy.

5.2.3 NICE Guidance

Clinicians must follow the NICE guidance which helps them and NHS organisations to:

- Provide patients with appropriate information about interventional procedures (NICE produces a lay version of the guidance for each procedure)
- Understand the circumstances under which a procedure is efficacious and safe enough for use
- Encourage gathering of further information where uncertainty exists (NICE produces audit support for procedures of uncertain efficacy and/or safety)
- Protect patients from inappropriate procedures.

NHS clinicians are responsible for notifying procedures to NICE where appropriate and for applying NICE guidance to meet the needs of individual patients. They are also responsible for applying NICE guidance, in their local context, in light of their duties to avoid unlawful discrimination and to promote equality.

'The NICE Intervention Procedures Committee particularly encourages the submission of statements on efficacy and safety outcomes that are of importance to patients. Descriptions of the benefits or harms of procedures that may only be identified by patients are also of interest, particularly those relating to quality of life' [1 (p27)]

5.2.4 Human rights and consent

Clinicians must take into consideration the requirements of the Human Rights Act 1998. In particular, patients' fully informed consent must be clearly

recorded as per the UHB Consent policy. It must include an understanding that the procedure is newly introduced, the global and personal experience and outcomes of the procedure, its anticipated benefits, possible adverse effects, and alternatives including the option of established equivalents.

Translation services may be required for anyone who does not have a comprehensive understanding of English – particularly given that new procedures may need very specific and detailed explanation. Health literacy would not have an impact on clinical decisions under this policy.

5.3 Clinical Board responsibilities

The Clinical Board Director, Nurse and Head of Operations and Delivery must ensure that:

- This procedure is adhered to and that all steps have been satisfactorily completed and agreed.
- An assessment of the clinical and financial impact on the overall service has been undertaken
- Appropriate arrangements are in place to monitor compliance against the Implementation of Interventional Procedures and NICE Medical Technologies Guidance.
- Relevant patient outcomes generated through clinical audit are discussed at appropriate Quality, Safety and Experience meetings and reported to Clinical Board Quality Safety and Experience meetings.
- All identified risks from new procedures are added onto the Directorate and Clinical Board Risk Registers.

6. RESOURCES

New procedures with revenue or other resource consequences will only be introduced after business planning approval.

7. TRAINING

'It is expected that clinicians/practitioners should be adequately trained to perform procedures within their specialty. Similarly, it is expected that clinicians/practitioners involved in the delivery of a diagnostic or therapeutic intervention that involves radiation exposure are accredited in its use.' [1 (p31)]

Any clinicians/practitioners in the UHB who are considering the use of a new interventional procedure which he/she has not used before, or only used outside the NHS, must have undertaken set standards of training, and be assessed as competent to undertake the procedure.

During training, the competency for performing clinical techniques and procedures is closely scrutinized. Once trained, the mechanism for acquiring new skills and introducing new procedures is less regulated.

8. IMPLEMENTATION

This procedure will be introduced and implemented by the Assistant Medical Director for Patient Safety and Innovation as follows:

- The policy and procedure documentation will be sent via the UHB e-mail system to:
  - Clinical Board Directors
  - Clinical Board Nurses or Quality and Safety Leads where there is no Clinical Board Nurse
  - Heads of Operations and Delivery
  - Clinical Directors
  - Directorate Lead Nurses
  - Directorate Managers
  - Assistant Medical Directors
  - Patient Safety and Quality Team

- Publishing the policy and procedure on the intranet page

- Signposting the policy and procedure via the weekly UHB Round UP

- Targeted presentations and discussions at established clinical meetings for example Quality, Safety and Experience meetings and protected quality and safety sessions.

Ensuring that a system is in place to police policy and procedure compliance by anyone involved in the implementation of a new procedure including clinicians, especially theatre, sterile services, radiology, endoscopy.

9. AUDIT/MONITORING

New procedures will be closely monitored by use of an agreed dataset. A central database of new procedures and outcomes will continue to be maintained by the Clinical Audit Department. Incident reports must be completed for any untoward events.

It is expected that, in their hospital assessments, The Health Inspectorate Wales (HIW) and other external agencies will include a check on the use of new interventional procedures and the clinicians who have notified NICE of their intention to perform them.

10. APPENDIX 1

CARDIFF AND VALE UNIVERSITY HEALTH BOARD

APPLICATION FOR THE INTRODUCTION OF A NEW CLINICAL PROCEDURE OR TECHNIQUE

e-mail or post to your Clinical Director for next step in gaining approval.
Copies of all approved applications should go to Clinical Audit Department
Clinical.Audit.cav@wales.nhs.uk

Section 1 – Submitting Clinician	
Name	
Status	
Specialty	
Directorate	
Address	
Phone/fax	
e-mail	

Section 2 – New Procedure/Technique	
a) Name of procedure (and any alternative names)	
b) Entirely new procedure, new to UHB, or new to you	
c) NICE listed or approved	
d) Similar to, or different from, established procedure	
e) Which existing procedure/s might it replace	
f) Brief description of what is involved in the procedure	

Section 3 – Clinicians involved	
a) Which specialties might perform this procedure	
b) Individual names/job titles of clinicians proposed	
c) Is training required (how will it be obtained)	
d) Is competence assured (how is it confirmed)	

Section 4 – Patients	
a) Which patients are likely to benefit	
b) The clinical indications for its use	
c) The reason for introducing this particular intervention	
d) What are the intended health benefits	
e) Possible adverse effects (and level of risk?)	
f) Can you estimate numbers/potential impact on NHS	
Section 5 – Evidence base	
a) Is this procedure in use elsewhere	
b) Details of conference proceedings/communications	
c) Details of peer reviewed papers	
Section 6 – Surveillance	
a) Is the procedure part of a clinical trial	
b) How will it be audited	
c) What patient information will be provided	
d) Confirm patients will be told status of new procedure	
e) Confirm adverse events will be incident reported	
f) Confirm NICE is aware of procedure/personnel	
Section 7 – Resources	
a) Do devices comply with EC standards	
b) Are devices certified for this use	
c) Are there cost implications (capital/revenue)	
d) Is a commercial organisation involved	
e) How will costs be met	
Section 8 – Probity	
a) Could there be any commercial interests	
b) Could there be any intellectual rights	
c) Could there be any conflicts of interest	
Section 9 – Approval	
Submitting Clinician – section 1	
New procedure Technique – section 2	
To be completed for applications from medical staff	
Name of Clinical Board Director:	

Approval granted?	Yes	No
If no please state reason:		
Signature of Clinical Director :		Date

Medical Director:

Approval granted?	Yes ☐	No ☐
If no please state reason		
Signature of Medical Director		Date

To be completed for applications from non-medical staff

Clinical Board Nurse/Directorate Manager

Approval Granted?	Yes ☐	No ☐
If no, please state reason		
Signature:		Date:

To be completed for all applications – next page
To be completed for all applications – Continued

Name of Directorate Manager

Approval granted?	Yes ☐	No ☐
If no please state reason		
Signature of Directorate Manager		Date

Name of Head of Operations and Delivery

Approval granted?	Yes ☐	No ☐
If no please state reason		
Signature of Head of Delivery		Date

Comments

Interest in entirely new procedures should also be notified to NICE using their web based form, navigating from http://www.nice.org.uk/page.aspx?o=ip