

New Interventional Procedures Policy

Policy information

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National Safety Standards for Invasive Procedures (NatSSIPs) standards: N/A

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Summary of document:

This policy sets out the governance for the introduction of new interventional procedures within Hywel Dda University Health Board. This will ensure that any new procedures introduced within the Health Board are safe, effective and support the best outcomes for patients.

Scope:

This policy applies to all staff employed by the Health Board who are involved with the introduction of a new interventional procedure. This includes:

- Healthcare professionals who wish to introduce a new interventional procedure
- Service managers of the clinical areas where new interventional procedures are being proposed

To be read in conjunction with:

[013 - NICE and Other National Guidance Implementation Policy](#) (opens in new tab) [Management of NICE and other National Guidance Policy].

[597 - Monitoring the Public Health Wales List of Procedures/Diagnoses Entitled INNU Procedure](#) (opens in new tab) [INNU Policy].

[005 - Clinical Audit Policy](#) (opens in new tab)

027 - R&D Strategy

[031 - Production of Patient and Carer Information Policy](#) (opens in new tab)

[008 - Consent to Examination or Treatment Policy](#) (opens in new tab)

[467 - Medical Devices Policy](#) (opens in new tab)

Patient information:

Owning group:

Effective Clinical Practice Advisory Panel date approved:

Executive Director job title:

Medical Director

Reviews and updates:

1.0 – New Policy

1.1 - Update to add Equality Impact Assessment details and other minor amendments

2.0 – Update following changes in management and reporting structures, with other minor amendments

3.0 – Full Review. Reuploaded – title change back to ‘New Interventional Procedures Policy’

4.0 – Full Review (reuploaded 30.11.2022 correction to flowchart)

5.0 – Full three yearly review 3.11.2025

Keywords

New Interventional Procedure, NICE, Interventional Procedures Guidance

Glossary of terms

AMD – Associate Medical Director

AWMSG - All Wales Medicines Strategy Group

ECPAP – Effective Clinical Practice Advisory Panel

CCG – Clinical Care Group

IPG – Interventional Procedures Guidance

MDG – Medical Devices Group

MMOG – Medicines Management Operational Group

NIP - New Interventional Procedure

NICE – National Institute for Health and Care Excellence

HTW – Health Technology Wales

OQSESC – Operational Quality, Safety and Experience Sub-Committee

QSEC – Quality, Safety and Experience Committee

R&I – Research and Innovation

Service Triumvirate - Clinical lead, Nursing lead, Service Delivery Manager

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Introduction

Innovation and the introduction of new interventional procedures are integral to the work of the NHS. This policy is designed to enable Hywel Dda University Health Board to apply governance to the introduction of new procedures. It will support the Health Board to make informed, evidence-based decisions about interventional procedures being introduced into clinical practice. It will also apply governance to procedures which National Institute of Health and Care Excellence (NICE) recommends should not be performed.

Policy statement

This policy is intended to support the Health Board in the introduction and monitoring of new interventional procedures. It is intended to improve effectiveness and safety of clinical care and reduce the risk of harm.

Scope

This policy applies to all staff employed by the Health Board who are involved with the introduction of a new interventional procedure. This includes:

- Healthcare professionals who wish to introduce a new interventional procedure
- Service managers of the clinical areas where new interventional procedures are being proposed

Interventional procedures are defined by NICE as procedures that involve incision, puncture and entry into a body cavity, or that use ionising, electromagnetic or acoustic energy. They can include things like:

- Making a cut or a hole to gain access to the inside of a patient's body, for example an operation or inserting a tube into a blood vessel.
- Gaining access to a body cavity without cutting, for example carrying out treatment inside the stomach using an instrument inserted via the mouth.
- Using electromagnetic radiation, for example using a laser to treat eye problems.

This includes new interventional procedures covered by NICE Interventional Procedure Guidance, Health Technology Wales guidance and other new interventional procedures which meet the criteria set out within this policy.

What is a 'new' Procedure

A new clinical procedure is any clinical intervention which involves new techniques which have not previously been undertaken within the Health Board, and it may also include the use of new equipment.

This can include:

1. Procedures never before undertaken anywhere
2. Procedures in use elsewhere but not within Hywel Dda University Health Board
3. An established procedure extended to a new condition, development of an established procedure or significant variation in technique
4. A new procedure emerging elsewhere within Hywel Dda University Health Board
5. Procedures that have been evaluated locally via the Tritech Institute and proposed for use in local practice

Aim

The aim of this document is to:

- Provide governance to the introduction of new interventional procedures or addressing interventional procedures which have been reviewed by NICE.
- The policy sets out the process for the introduction of new interventional procedures and is designed to enable clinicians to embrace new interventions whilst ensuring adequate controls are in place to protect patients and reduce risk.

Objectives

The aim of this document will be achieved by the following objectives:

- Ensuring that any new interventional procedures introduced within the Health Board are safe and work well enough for wider use in the NHS;
- Ensuring that any new interventional procedures introduced within the Health Board have robust evidence to support their use in clinical practice;
- Ensuring that any associated risks are recognised and managed;
- Ensuring that their introduction is robustly monitored to establish safety and outcomes;
- Ensuring that new interventional procedures deemed by NICE as lacking sufficient evidence with regard to safety or efficacy, are assessed and, where appropriate, removed from practice.

Approval of New Interventional Procedures

NICE New Interventional Procedures

NICE Interventional Procedures Guidance (IPG) looks at procedures used for diagnosis or treatment. It considers if they are safe and work well enough for wider use in the NHS, and also whether special arrangements are needed for clinical governance, consent, and audit.

The guidance protects patients' safety and makes it possible for new treatments and tests to be introduced into the NHS in a responsible way.

There are four types of recommendation that NICE can make regarding whether the NHS should consider offering certain interventional procedures:

- Can be used** – this recommendation is a positive recommendation and means that there is enough evidence to show that a technology provides benefits and value for money, so it can be used routinely across the NHS. Clinicians don't have to offer this procedure to patients and should always [discuss the available options with the patient before making a decision](#) (opens in new tab) Clinicians must also follow the Health Board's policy about getting permission to perform operations and monitoring the results.
- Can be used during either:**
 - A managed access period (for technology appraisals and highly specialised technologies).
Some technologies have a managed access agreement. A recommendation of this type means the technology can be used in the NHS during the managed access period. Managed access gives people faster access to promising new treatments. [Find out more about managed access](#). (opens in a new tab).

- Evidence generation period (for medical technologies, diagnostics, early value assessments and interventional procedures)
Some promising technologies can be implemented while evidence is generated on their clinical effectiveness and value for money. This type of recommendation applies specifically to medical technologies, diagnostics, early value assessments and interventional procedures. It means a technology can be used while evidence is being generated in line with an evidence-based generation plan (if applicable). Find out more on [Early Value Assessment \(EVA\) for medtech | NICE](#) (opens in a new tab).
- c. **More research is needed** - this type of recommendation means that a technology has potential to provide benefits, but there is not enough evidence to support using it routinely in the NHS. It should only be used in research. The procedure should only be carried out in the context of formal research studies, as approved by a research ethics committee.
- d. **Should not be used** – The evidence suggests that this technology does not offer sufficient benefit or value for money, so it should not be used routinely in the NHS. For interventional procedures, the evidence will have shown that the procedure does not work well enough, or that there are unacceptable safety risks. NICE make this recommendation if the evidence suggests that the procedure doesn't work well, or if there are unacceptable safety risks.

If the procedure is the subject of a NICE IPG, the proposed use of the procedure must comply with the guidance.

Health Technology Wales Guidance

Health Technology Wales (HTW) is a national body working to improve the quality of care in Wales. HTW collaborate with partners across health, social care and the technology sectors to ensure an all-Wales approach. Their remit covers any technology or model of care and support in health and social care that isn't a medicine. For health, this could include medical devices, diagnostics, procedures and psychological therapies.

HTW aim to improve the quality of health and social care in Wales by assessing the value and optimising the use of clinically- and cost-effective technologies and models of care and support. HTW assess non-medicine health and social care technologies and models of care and support, and issue independent, authoritative guidance based on the best available evidence and expertise. Any guidance issued by HTW in relation to interventional procedures will therefore be within the scope of this policy.

If NICE has not published an IPG for the procedure, or there is no Health Technology Wales Guidance the Health Board can still approve it as long as:

- There is a robust body of evidence and extensive supporting data, such as well-established research
- The clinician has appropriate training and experience
- Patients are made aware of the circumstances under which the procedure is being performed, and consent to this
- Arrangements are made for data collection and robust monitoring
- The following Health Board procedure has been followed:

Deciding to Undertake a New Interventional Procedure

If a healthcare professional becomes aware of a new interventional procedure that may be of benefit to patients within the Health Board, they must first discuss its potential implementation with their Clinical Lead and Service Triumvirate. In doing so they should:

- Confirm that the procedure is not already undertaken anywhere else in the Health Board
- Give consideration to the procedure's place in the clinical pathway (e.g. whether it is an addition, an adjunct or a replacement for existing procedures)
- Agree at which hospital sites it could be used
- Consider whether it would be clinically and cost effective to implement

Criteria for Procedures Requiring Approval

If the Clinical Lead and Service Triumvirate agree that the proposed procedure may be an appropriate addition to service delivery, it will need to be formally approved prior to implementation. Any new interventional procedure which fulfils one or more of the following criteria must receive specific approval for use within the Health Board:

- a. An established procedure extended to a new condition, development of an established procedure or significant variation in technique
- b. A new procedure emerging elsewhere within Hywel Dda University Health Board

This includes procedures that fall into the NICE Interventional Procedure Guidance category *Can be used* and *Can be used during either a managed access period or evidence generation period*.

For procedures never before undertaken anywhere and procedures that fall into the NICE Interventional Procedure Guidance category *More research is needed* please see section ['Procedures that require Research'](#).

For procedures that are in use elsewhere but not within Hywel Dda University Health Board please see section ['Procedures that Require Local Evaluation'](#).

For procedures that have been evaluated locally through the Trittech Institute and proposed for use in local practice please see section ['Procedures subject to Trittech Institute Evaluation'](#).

For procedures that fall into the NICE Interventional Procedure Guidance Category *Do Not Use* please see section ["Do Not Use' Procedures"](#).

If there is doubt as to whether the criteria apply to a particular procedure, the healthcare professional should request advice from the Effective Clinical Practice Advisory Panel.

If it is clear that the proposed procedure does not meet one or more of the above criteria, it does not need formal approval.

New Interventional Procedures Approval Process Support

The responsibility for seeking approval to introduce a new interventional procedure is delegated to the specialty Clinical Lead and Service Triumvirate. The Clinical Director for Effective Clinical Practice and the Clinical Effectiveness Co-ordinator will support the submission process.

Healthcare professionals wishing to introduce a new interventional procedure must discuss this with their specialty Clinical Lead and Service Triumvirate.

Completing an Application

Once it has been identified that a proposed new interventional procedure requires formal approval, the proposing healthcare professional must complete the [New Interventional Procedures Form](#) (opens in new tab). All sections of the form must be completed in full, and with sufficient detail to enable the specialty Clinical Lead and Service Triumvirate to make an informed decision. The completed form will be held centrally, and the Clinical Effectiveness Coordinator will receive notification of submission, the Clinical Effectiveness Coordinator is also available for support in completing the proforma if required.

The completed form must be signed off by the specialty Clinical Lead and Service Delivery Manager, both of whom should consider the proposed procedure in the light of other Directorate priorities.

- The specialty Clinical Lead should give consideration to the appropriateness of the procedure; its place in the clinical pathway; the evidence base behind it; and the potential benefits to patients.
- The Service Delivery Manager should give consideration to the financial and other resource implications (and how they balance against other organisational priorities); the practicalities of introduction; and the impact on the service, including the impact on adjacent services (e.g. diagnostics/ theatre time etc). They are specifically asked to confirm whether the procedure can be implemented within the existing budget. If there is a requirement for new equipment or devices, the [467 - Medical Devices Policy](#) (opens in new tab) must be adhered to.

If the specialty Clinical Lead and Service Delivery Manager support the introduction of the procedure, the proforma should be submitted, and it will be automatically captured centrally.

If neither the specialty Clinical Lead and Service Delivery Manager support the application, but the proposing healthcare professional feels strongly that it should be considered by the Effective Clinical Practice Advisory Panel, the healthcare professional can appeal to the Medical Director who will decide whether or not the proforma can be submitted to the Effective Clinical Practice Advisory Panel for consideration.

Submitting an Application

Once a decision has been made to submit the application, it must be completed electronically using the following form: [New Interventional Procedures Form](#) (opens in new tab). The proforma is then automatically included on the central register.

Considering an Application

The application should then be discussed at the next appropriate Integrated System Service Group/ Clinical Service Group and then discussed at the relevant Clinical Care Group meeting for consideration and full approval. The Clinical Effectiveness Coordinator will prepare the application form and ensure inclusion on the agenda of the next suitable meetings, alongside a copy of the NICE Interventional Procedure Guidance (if relevant) and any other supporting information.

When considering the application, the appropriate Integrated System Service Group/ Clinical Service Group and the relevant Clinical Care Group should seek assurance that:

- The healthcare professional has met appropriate external standards of training to undertake the procedure in question
- Indemnity has been checked
- There is a sound evidence base for the introduction of the procedure
- Proposed arrangements for monitoring and/or clinical audit are sound, in line with the recommendations in the NICE Interventional Procedure Guidance (if relevant) and will capture data and clinical outcomes that will be used to review continued use of the procedure and clinical competency for future use
- Any resource requirements relating to the new procedure have been identified and can be met, including that the Medical Devices Group has approved any new equipment required
- Written information for patients in relation to the procedure are available

Approving an Application

If the application is supported at the appropriate Integrated System Service Group/ Clinical Service Group and the relevant Clinical Care Group, the decision is shared for final senior clinical sign-off by the Deputy Medical Director for Acute Hospital Services or Deputy Medical Director for Primary Care and Community Services.

Any parameters for future review are discussed and recorded.

The decision is discussed at the Effective Clinical Practice Advisory Panel and logged centrally by the Clinical Effectiveness Coordinator.

If the application is not supported but the proposing healthcare professional feels strongly that it should be considered by the Effective Clinical Practice Advisory Panel, the healthcare professional can appeal to the Medical Director who will decide whether or not the application can be discussed by the Effective Clinical Practice Advisory Panel.

Outcome

The final outcome is logged centrally and the following stakeholders within the Clinical Care Groups are notified:

- Proposing healthcare professional
- Specialty Clinical Lead
- Service Delivery Manager
- Clinical Care Group Service Director
- Associate Medical Director
- Assistant Director
- Clinical Director
- General Manager

The following stakeholders will also be notified, for information:

- Service Delivery Teams for Theatres and Endoscopy (where relevant)
- Medical Devices Group (where MDG approval of equipment is required)
- Supply chain managers, including Capital and Procurement (where purchase of equipment is required)
- Medicines Management Operational Group (where relevant)
- Clinical Audit Manager (where relevant)

- Patient Experience Manager (where relevant)
- Head of Consent and Mental Capacity

The Quality, Safety and Experience Committee will be informed of the outcome via the Effective Clinical Practice Advisory Panel update report.

Procedures Approved for Use

If a proposed new interventional procedure is approved, the clinician undertaking the procedure must maintain and be able to provide the following information if requested by the Effective Clinical Practice Advisory Panel:

- Evidence that the clinician(s) undertaking the procedure has/have the appropriate training and experience;
- Evidence that patients are made aware of the circumstances under which the procedure is being performed, and consent to this (Refer to [008 - Consent to Examination or Treatment Policy](#) (opens in new tab)).
- Introduction of special arrangements around patient consent, including informing the patient of any lack of experience in use of the procedure (Refer to [008 - Consent to Examination or Treatment Policy](#) (opens in new tab)), and clearly describing any other risks involved.
- Evidence that arrangements are in place for data collection and clinical audit;
- Data which demonstrates complication rates, clinical outcomes and patient satisfaction with the procedure.
- Evidence that any related clinical audit project has been registered with the Clinical Audit Department and identified as a New Interventional Procedure Audit (Refer to [005 - Clinical Audit Policy](#) (opens in new tab)).

In addition, where implementation of a new interventional procedure involves the purchase of new equipment, or the use of existing equipment for a different purpose, the approval will be 'in principle', pending the approval of the device for use by the Clinical Engineering Department and the Medical Devices Group. Once the Clinical Engineering Department and Medical Devices Group have given their approval, the new intervention will be deemed as 'approved'. The Medical Devices Group will inform the NWSSP procurement that the equipment has been approved for use.

Where the new interventional procedure involves a medicine for a new or different purpose, it will need to be approved by the Medicines Management Operational Group. In these circumstances the approval will be 'in principle' pending the approval of Medicines Management Operational Group.

These conditions, and any requirement to obtain approval from Medical Devices Group and/or Medicines Management Operational Group, will be included in the communications to the stakeholders listed above.

If the healthcare professional subsequently ceases to use the approved interventional procedure the Clinical Effectiveness Co-ordinator/Effective Clinical Practice Advisory Panel must be notified. This can be achieved by directly informing the Clinical Effectiveness Coordinator or through this generic e-mail address: clinical.standardsandguidelines.hdd@wales.nhs.uk

Procedures not Approved for Use

If a proposed new interventional procedure is not approved for use, the proposer will be informed in writing that they must not use the procedure within the Health Board. This decision, and the reasons for it, will be sent to the stakeholders listed above.

Where relevant, Medical Devices Group and the NWSSP procurement will be notified that equipment specifically related to the procedure should not be purchased.

Insufficient Information for a Decision to be Made

If the specialty Clinical Lead and Service Delivery Manager decide that additional information is required before they can make an informed decision they will either:

- Ask the proposer to supply the additional information; or
- Refer to the Effective Clinical Practice Advisory Panel for further advice, including a request for the Panel to consider the application following a presentation of the case

Urgent Approval of a New Interventional Procedure

If a patient requires an emergency procedure which, under normal circumstances, would require approval (because the procedure meets with one or more of the criteria contained within this policy), the following steps should be followed (where time permits):

The specialty Clinical Lead or Directorate Clinical Director (or Manager on call) should be contacted by the healthcare professional and informed of:

- Why the particular procedure is required and what the alternatives are (if any)
- Why it needs to be undertaken as an emergency
- What the procedure involves
- The skills and experience of the healthcare professional in undertaking the procedure
- The risks to the patient (of having or not having the procedure)
- And whether the theatre/endoscopy staff have the appropriate skills and equipment to support the healthcare professional in undertaking the procedure.

The specialty Clinical Lead or Clinical Director will then make a decision regarding whether or not the procedure should go ahead on a one-off basis, pending full approval (following the process outlined in above). The decision making and outcome should be clearly documented within the patient records.

It is the responsibility of the specialty clinical lead or Clinical Director to notify the Clinical Effectiveness Co-ordinator that such a procedure has been undertaken and requires formal approval if future use is planned.

Procedures that Require Local Evaluation

For procedures that are in use elsewhere but not within Hywel Dda University Health Board a local evaluation is required alongside implementation. The Tritech Institute may serve as a valuable resource for teams across the organisation, providing support in generating local evidence where existing data is limited or unavailable. This approach facilitates informed decision-making and contributes to the broader evidence base for innovation adoption.

As above, an application should be submitted but this will need to be accompanied by evaluation outcomes.

Procedures Subject to TriTech Institute Evaluation

The TriTech Institute (<https://tritech.nhs.wales/> (opens in new tab) supports the evaluation and development of healthcare solutions on a local, national, and global level offering designers and manufacturers a single point of access to the NHS through a collaborative and agile approach. The TriTech team are comprised of clinical scientists, researchers, engineers, data scientists, nurses, pharmacists and doctors who conduct research and real-world evaluations on healthcare innovations.

Technologies (including devices and digital) that have been evaluated locally through the TriTech Institute and proposed for use in local practice should be approved subject to favourable clinical, patient or cost outcomes and agreed by the service lead.

As above, an application for approval should be submitted but this will need to be accompanied by a copy of the interim or final reports. The application should be discussed at the next appropriate Integrated System Service Group/ Clinical Service Group and the relevant Clinical Care Group meeting for consideration and full approval.

Procedures that require Research

Procedures never before been undertaken anywhere, or procedures that fall into the NICE Interventional Procedure Guidance category *Use only in Research* must not be undertaken until a research application has been made and has been approved by the Health Board Research and Innovation Department (researchsupport.hdd@wales.nhs.uk (opens in new tab) and the appropriate Research Ethics Committee.

In some cases where the project covered by the research application is considered particularly complex or high risk, it will be sent to the Joint Scientific Review Committee (JSRC) based in Swansea Bay University Health Board and Swansea University, for review.

If the procedure described in the NICE Interventional Procedure Guidance is already being undertaken within the organisation, but the guidance indicates that the procedure must be used only in research, then either:

- Its use must cease until a research application has been made and has been approved by the Health Board Research and Innovation Department and the appropriate Research Ethics Committee (as above)
- If there is no intention to participate in a research study then its use must cease immediately. The clinicians using the procedure and the Service Triumvirate will be informed of this requirement in writing by the Clinical Effectiveness Co-ordinator so that they can take appropriate action. This information will be logged centrally.

‘Should not be used’ Procedures

Procedures that fall into the NICE Interventional Procedures category ‘should not be used’ will not be considered for use within the Health Board, and existing use of any procedures in this category being undertaken within the Health Board must cease immediately.

If it is discovered that a 'should not be used' procedure is in use, the clinicians using the procedure and the Service Triumvirate and Management Team will be informed in writing by the Clinical Effectiveness Co-ordinator of the requirement to cease this procedure immediately, so that they can take appropriate action. The clinicians undertaking the procedure will be asked to provide an explanation of why they have been using this procedure, and this information will be discussed at the Effective Clinical Practice Advisory Panel and logged centrally.

Notifying a Novel Procedure to NICE

New interventional 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 procedure¹.

Notification can be made via the NICE website: [Interventional Procedures Notification Form](#) (opens in new tab) and will be supported by the Clinical Effectiveness Co-ordinator where required.

Clinicians can contact the NICE Interventional Procedures Programme team for advice on whether it is appropriate for a procedure to be notified to the Programme.

If the procedure is within the scope of the programme clinicians should delay undertaking the procedure until a decision has been made regarding the safety and efficacy of its use. If the healthcare professional wishes to undertake the procedure in the interim, for the protection of their patients and themselves, they should follow the procedure outlined above, ensuring that they inform the specialty clinical lead that the NICE Interventional Procedures Programme has been notified of the procedure. Clinicians will be expected to notify the NICE Interventional Procedures Programme of their intention to perform a registered procedure. The Health Board would view failure to do so as a significant clinical governance risk which would be escalated to the relevant Executive Director.

Consent

The information given prior to consent by a patient must include specific reference to the fact that the technique or procedure is new. Patients need to understand that the procedure's safety and efficacy may be uncertain and must be informed of the anticipated benefits and possible adverse effects of the treatment and of the alternatives, including no treatment. If written consent is not usually required for the normal procedure, consideration should be given to seeking written consent as a means of documenting the information given to the patient and their agreement to it.

Refer to [008 - Consent to Examination or Treatment Policy](#) (opens in new tab).

Audit and Monitoring

Any new technique or procedure introduced to the Health Board must have guidance developed to accompany it and must be subject to ongoing monitoring and/or audit. The proposal for introduction must include arrangements for that monitoring.

Results of this monitoring must be reported to the Effective Clinical Practice Advisory Panel. The frequency of monitoring activities will depend on the intervention. Under normal circumstances, the Effective Clinical Practice Advisory Panel will ask for a report from the clinician on the first 20 patients treated. For less frequently performed interventions or procedures, the Effective Clinical Practice Advisory Panel will require a report from the clinician after the first 6 months of introducing the intervention or procedure, if 20 patients have not been treated by that time.

Refer to [005 - Clinical Audit Policy](#) (opens in new tab).

Adverse Incident Reporting

Any adverse incident or near miss which occurs when undertaking a new intervention or procedure must be reported immediately on Datix via the intranet in accordance with the Health Board's Incident Reporting Procedures. When entering details on the electronic incident form it must be clearly stated that the incident occurred during the course of a new interventional technique or procedure.

Responsibilities

Chief Executive

Has overarching responsibility for ensuring that interventional procedures undertaken in the Health Board are safe and evidence based, and that there are appropriate processes in place for the introduction of new techniques. This responsibility is delegated through the Medical Director.

Medical Director

Holds delegated responsibility for clinical effectiveness issues.

- Makes final decisions in the case of disputes over whether a procedure should be discussed by the Effective Clinical Practice Advisory Panel
- Receives information provided by the Effective Clinical Practice Advisory Panel following the consideration of the application.

Assistant Director, Medical Directorate

Responsibility for dissemination and monitoring of New Interventional Procedures Guidance; and co-ordination of processes and provision of support to proposing clinicians.

Proposing Clinician

The proposing clinician is responsible for:

- Comprehensive completion of the required proformas following discussion with Service Delivery Team;
- Implementation of decision in line with the agreement reached, and any conditions imposed;
- Provision of feedback to the appropriate Integrated System Service Group/ Clinical Service Group regarding governance and monitoring arrangements in place, and any associated data, at regular intervals.

Speciality Clinical Leads

Speciality Clinical Leads are responsible for:

- Supporting individual clinicians in the introduction of a new interventional procedures and acting as sponsor for the new interventional procedure proposal
- The approval of the relevant proforma having considered appropriateness of the procedure; its place in the clinical pathway; the evidence base behind it; staff competencies and the potential benefits to patients
- Referring to the Effective Clinical Practice Advisory Panel for further advice where a decision cannot be reached to approve the proforma, including a request for the clinician to present their case to the Panel
- Taking appropriate action to ensure the decision is implemented within the service

Service Delivery Manager

The Service Delivery Manager is responsible for:

- Approval of the relevant proforma having considered the financial and other resource implications; the practicalities of introduction; and the impact on the service
- Taking appropriate action to ensure the decision is implemented within the service

Service Delivery Team (Clinical Lead, Senior Nurse Manager/Lead Nurse and Service Delivery Manager)

The Service Delivery Team has responsibility for:

- The initial consideration and approval or rejection of a proposal for the introduction of any new intervention or technique, prior to submission to the appropriate Integrated System Service Group/ Clinical Service Group.
- Ensuring that the monitoring of outcomes and audits related to the effectiveness of the new intervention/technique are monitored. The group is responsible for escalating any issues arising from any monitoring and audits to the appropriate Integrated System Service Group/ Clinical Service Group.

Integrated System Service Group/ Clinical Service Group and Clinical Care Groups

The appropriate Integrated System Service Group/ Clinical Service Group and Clinical Care Group has responsibility for:

- Approving or rejecting a proposal for the introduction of any new intervention or technique, prior to submission to the Deputy Director for Acute Hospital Services or Deputy Director for Primary Care and Community Services
- Ensuring that this policy has been adhered to
- Assuring themselves that the new procedure is being monitored effectively. Where there is no appropriate Integrated System Service Group/ Clinical Service Group or relevant Clinical Care Group, the relevant Triumvirate Team will need to assure themselves that the monitoring of outcomes and audits related to the effectiveness of the new intervention are being monitored by an appropriate group. The outcome of the introduction of any new procedure must be reported to the Effective Clinical Practice Advisory Panel

Individual Clinicians

Individual clinicians have responsibility for:

- The introduction of any new interventional procedure to their patients, including providing appropriate information and gaining appropriate consent
- Ensuring that before any new interventional procedure is introduced Health Board agreement is obtained in accordance with this policy
- Ensure that the effectiveness and outcomes of any new interventional procedure is undertaken using robust methodologies
- Ensuring any audits of the effectiveness and outcomes of any new interventional procedure is registered with the Clinical Audit Department
- Reporting the results of monitoring activity to the relevant Integrated System Service Group/ Clinical Service Group, Clinical Care Group and the Effective Clinical Practice Advisory Panel
- Notifying the procedure to the Interventional Procedures Programme at NICE

Effective Clinical Practice Advisory Panel

Hywel Dda University Health Board

The Effective Clinical Practice Advisory Panel is responsible for:

- Providing advice to healthcare professionals if there is doubt as to whether the criteria for approval of a new interventional procedure apply to a particular procedure.
- Receiving appeals if neither the specialty Clinical Lead and Service Delivery Manager support the application, but the proposing healthcare professional feels strongly that it should be considered by the Effective Clinical Practice Advisory Panel, if the Medical Director deems that the proforma can be submitted to the Effective Clinical Practice Advisory Panel.
- Including in a six-monthly report to the Quality, Safety and Experience Group all new interventional procedures approved
- Providing oversight and scrutiny of decisions to introduce new interventional procedures
- Ensuring that any parameters set in the approval of the new interventional procedure are met
- Requesting relevant information on outcomes and receive regular reports on new procedures registered and approved
- Dissemination of final decision to the appropriate Integrated System Service Group/ Clinical Service Group, the relevant Clinical Care Group and Clinical management teams.

Clinical Director for Effective Clinical Practice

The Clinical Director for Effective Clinical Practice is responsible for:

- Provision of advice to clinicians regarding whether a new interventional procedure meets with the criteria contained within this policy
- Advice on the completion of the proforma if required
- Liaison with Medical Devices Group where an approved procedure requires separate approval of the required equipment

Medical Devices Group

The Medical Devices Group is responsible for:

- Consideration of any potential equipment issues associated with the proposal, when new equipment is being proposed.
- Providing approval where introduction of a new interventional procedure would require the purchase of new equipment, or a change in use of existing equipment.
- Where the equipment has not previously had Medical Devices Group approval or where the equipment is the source of the uncertainties identified by NICE, the Medical Devices Group must consider approval of the equipment's continued use Refer to [467 - Medical Devices Policy](#) (opens in new tab) and appropriate risk considerations, in relation approval of the procedure.

Research and Innovation Department

The Research and Innovation Department is responsible for:

- Consideration of research applications for procedures never before been undertaken anywhere, or procedures that fall into the NICE Interventional Procedure Guidance category *Use only in Research* and approval where criteria are met including the appropriate Research Ethics Committee (Refer to HDUHB Strategy 27 - R&I).
- Provision of advice to clinicians regarding study design, funding, approval process and quality assurance.
- Agreeing sponsorship of research through Sponsorship Review Group.
- For projects covered by a research application that are considered particularly complex or high risk, referring the project to the Joint Scientific Review Committee (JSRC) based in Swansea Bay University Health Board and Swansea University, for review.

References

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Website of the National Institute for Health and Care Excellence: www.nice.org.uk (opens in new tab).

Bristol Royal Infirmary Inquiry, *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 –1995*, Command Paper: CM 5207, 2001.
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005620 (opens in new tab).

[Medical Devices Regulations 2002 \(SI 2002 No 618, as amended\) \(UK MDR 2002\)](#) (opens in new tab).

Further Information

NICE: www.nice.org.uk. (opens in new tab).

Appendix 1 – New Interventional Procedures Flowchart

