

Policy for the Introduction of New Procedures, Techniques or Major Changes in Clinical Practice

Department / Service:	All Clinical Services
Originator:	
Accountable Director:	Chief Medical Officer
Approved by:	Clinical Governance Group 5 th July 2022 Trust Management Executive
Date of approval:	20 th July 2022
First Revision Due:	20 th July 2025
This is the most current document and should be used until a revised version is in place	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All Clinical Departments
Target staff categories	All Medical and Dental Divisional Operational Teams

Policy Overview:

This Policy seeks to inform and guide Trust staff wishing to propose the introduction of new procedures or techniques to the Trust, or who wish to implement major changes in clinical practice, by detailing some of the relevant issues and outlining the process by which proposals will be considered.

Key amendments to this document

Date	Amendment	Approved by:

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Equality Impact Assessment
Financial Risk Assessment

Aims

This Policy seeks to inform and guide Trust staff wishing to propose the introduction of new procedures or techniques to the Trust, or who wish to implement major changes in clinical practice, by detailing some of the relevant issues and outlining the process by which proposals will be considered.

Scope & Definitions

NICE define an interventional procedure as a procedure used for diagnosis or for treatment that involves:

- making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel, or
- gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
- using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

For this purpose, new procedures include:

- New techniques including major modifications of current procedures.
- Established procedures which are new to the Trust, even when the consultant is experienced in this procedure.
- Established procedures which are new to the consultant who is using it for the first time in his or her NHS practice.
- New devices e.g. Prosthesis.

N.B.

Major changes in clinical practice or changes to published Trust guidelines are considered by the Clinical Governance Committee and the Trust Management Executive Committee.

For the purposes of this Policy, all new procedures; techniques or major changes in clinical practice are referred to as 'new procedures'.

Background

Medical practitioners planning to undertake new interventional procedures should seek approval from the Trust's Trust Management Committee before doing so. In a case where the procedure has to be used in an emergency, the procedure should be notified to the Chair of the Clinical Governance Group and Chief Medical Officer within 72 hours.

The Trust may consider a number of cases when making decisions on whether to approve the introduction of new procedures, techniques or major changes in clinical practice. These include the clinical case, the business case and the commercial case. Not all applications will require the completion of a commercial case or business case.

Process

The Trust Management Executive Committee will review clinical, business and commercial cases when considering whether to approve proposals submitted under this Policy.

It is anticipated that all proposals should consist of a clinical and business case, though proposals that have minimal financial implications may not require the presentation of a full business case. Proposals concerning major changes to practice which may potentially impact on networked or regional service provision should also include a commercial case.

All business cases **MUST** be presented to the Strategy and Planning Group for approval, with the clinical case, before proceeding to the Trust Management Executive Committee.

Should there be significant doubt whether a commercial case will need to be presented, an opinion from the Trust Management Executive Committee should be sought prior to submission.

An application will be considered incomplete unless all cases are presented to the Trust Management Committee simultaneously.

The essential elements of each case are outlined below.

Clinical Case

This will be prepared by the proposing clinician with assistance from the Clinical Service Lead and/or Clinical Director.

The clinical case seeks to establish the clinical effectiveness (including relevant NICE guidance), training and mentoring needs, safety and risk management concerns, patient information and consent and clinical audit plans of the proposed change. The application form template for the clinical case is available in appendix 1.

Business Case

This will be prepared by the proposing clinician in conjunction with the appropriate Divisional Management, with input especially from the Divisional Manager and Divisional Finance Manager.

The short business case seeks to establish the fundamental financial viability of the proposed change by detailing all costs, including equipment and workforce, associated with the proposed change together with agreed commissioner funding arrangements and any other financial concerns.

All business cases **MUST** be presented to the Strategy and Planning Group for approval before proceeding to the Trust Management Executive Committee.

Commercial Case

The commercial case will be prepared by the proposing clinician and/or Divisional Manager and will seek to establish whether the proposed changes are in line with the Trust's strategy. A commercial case will not usually need to be made for changes unlikely to substantially alter existing service demand.

Roles and Responsibilities

Clinical Governance Committee

The Committee will approve all new procedures, ensuring that the clinical, business and, where indicated, commercial cases have been made to its satisfaction.

The Clinical Governance Committee will act on behalf of the Trust Board to assure the Trust that there is compliance with the policy

Trust Management Executive Committee

Once approved, the Committee will ensure that the clinician introducing the procedure returns at a specified interval with an evaluation of the safety, effectiveness and cost-effectiveness of the procedure.

Clinical Director and Divisional Manager

Will assist clinicians with identifying costs for example, training in the new procedure, additional workforce requirements, additional theatre space and preparation of a business case.

Will ensure the development is included in the Divisional service plan when approved by the Trust Management Executive Committee.

Divisional Management Teams need to identify the source of revenue and capital funding for the new procedure including funding provided by commercial and other organisations and describe these in the business case.

Will discuss with the relevant commissioning body (CCG), and agree support or not, if appropriate.

Lead Clinician

Will discuss the proposal with the relevant Clinical Director, Divisional Management Teams and if appropriate the relevant commissioning body (CCG), and agree to support or not.

Will ensure that other departments and disciplines that may be affected by the development have been involved in the application form and provide details in the business case.

Clinician introducing the procedure

Will check whether the procedure has been evaluated or approved by NICE, by visiting their website www.nice.org.uk/guidance

Will check if the new procedure requires any products to be brought into the Trust. If this is the case, the Medical Devices Management Services (MDMS) must be made aware so that they can check Indemnity status and advise on how to proceed with regard to recording of those products, the duration in the Trust, and if there is a need for Portable Appliance Testing (PAT) review or decontamination.

Will complete application form (see Appendix 1) including gaining signatures indicating clinical case approval from Lead Clinician, Clinical Director, Divisional Director, Divisional Finance Manager and Chief Medical Officer.

Keep patient informed - in all cases it is the responsibility of the clinician using a new health procedure to ensure that his or her patient is fully informed of the risks and benefits of the technique supported by full written consent indicating that they are fully informed.

Will agree to undertake a clinical audit of the outcome of the use of the new procedure within one year of introduction into practice.

Will return to the Trust Management Executive Committee (TME) at a specified interval after the new procedure has been approved with an evaluation of the safety, effectiveness and cost-effectiveness of the procedure.

Monitoring

Clinical Audit

An audit of the new procedure will be undertaken no more than one year after its introduction. The results will be presented to the Clinical Governance Committee.

Risk Management

Should any potential risks be identified, these will be reported by the Divisional Management Team at the appropriate Performance Review meeting. A risk assessment and addition to the risk register may be required.

References and associated documents

Sources of Information

National Institute for Health and Care Excellence <https://www.nice.org.uk/>

Into Practice Guide National Institute for Health and Care Excellence <https://www.nice.org.uk/about/what-we-do/into-practice/resources-help-put-guidance-into-practice>

Appendices

Appendix 1: Form for completion



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w-procedures-policy

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Clinical Governance Group
Trust Management Executive

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	No	
6.	What alternatives are there to achieving the policy/guidance without the impact?	No	
7.	Can we reduce the impact by taking different action?	No	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval