The Royal Wolverhampton NHS Trust

OP95
Introduction of New Clinical Techniques and Interventional Procedures

Contents

1.0 Policy Statement (Purpose / Objectives of the policy)

1.1 The Royal Wolverhampton NHS Trust recognises the need for innovation and views the introduction of new clinical techniques and procedures as a vital part of practice to improve patient care and enhance the patient experience.

1.2 This must be balanced with the corporate responsibility for ensuring the safety of patients involved in the introduction of such clinical techniques and procedures.

1.3 The Trust must ensure that when new techniques and procedures are introduced within the organisation they are appropriate, effective and that all staff undertaking or involved in the procedure are properly trained.

1.4 This policy describes the review and approval process to be applied by all staff prior to the introduction of a new clinical technique or interventional procedure into practice.

1.5 An approval process for the use for new medication exists separately within the Medicines Management policies. The new procedure application process within this policy will apply where the new medication is to be used as part of an interventional procedure and, or used outside of its recommended indications or license.

2.0 Definitions

2.1 Interventional Procedure One used for diagnosis or treatment that involves an incision or puncture, or entry into a body cavity, including endoscopy; or , electromagnetic or acoustic energy.

An interventional procedure must be considered new if a clinical professional no longer in a training post is using it for the first time in his or her NHS clinical practice.

2.2 New procedure New procedures may fall into one of the following four categories.

1. The application of existing proven techniques to a new indication.
2. The application of new or existing proven techniques to be carried out by a specific clinical or professional staff member who is extending their role.

   “Extended roles" are roles which have additional or new duties, tasks or competence requirements. These roles may require broader or deeper knowledge, skills and understanding in order to meet changing service needs.
3. A significant variation in technique, new equipment or new device (refer to *HS 11 Management of Medical Devices* for authorization on the device) used during the course of a standard procedure; i.e., whether the new technique is likely to have a different safety and efficacy profile from that of the original procedure.
4. A procedure that has not been done at the Royal Wolverhampton NHS Trust even if the clinician is fully competent to undertake it.

These may be combined in such ways that a new device or technique opens the way for the management of a condition perhaps not previously treated or managed in a totally different way.

2.3 The specialty lead or lead clinician is the lead specialist for the new procedure or technique. They may be the applicant who will carry out the new technique or procedure or the Clinical Director or professional lead.

3.0 Accountabilities and Responsibilities

3.1 **The Trust Chief Medical Officer** is accountable for monitoring the effectiveness of this policy and compliance with the process for introducing new clinical techniques and procedures into the organisation.

3.2 **The Clinical Director or Professional Lead** is responsible for the initial sign off of the application following discussion with the applicant and other relevant stakeholders (e.g. Commissioners, Research and Development (R&D), or other services), and for submission of the application for Divisional approval and sign-off prior to submission to the Quality and Safety Advisory Group (QSAG).

3.3 Clinicians

3.3.1 All clinicians are personally accountable for their practice. In exercising this professional accountability, they must acknowledge any limitations in their knowledge and competence, and they must not undertake any duties or responsibilities unless they have received relevant training and assessment to perform them in a safe and skilled manner.

3.3.2 Clinicians wishing to undertake a new intervention must consider carefully whether this falls within the scope of the above definitions. If in doubt, they must assume that the intervention does fall within the definitions.

3.3.3 Clinicians wishing to introduce into the Trust a new clinical technique or procedure not previously undertaken before on the basis that NICE has issued guidance (Interventional Procedure Guidance (IPG) or Medical Technology Guidance (MTG)) must seek prior approval in accordance with this Policy.

Clinicians must check by visiting the NICE website www.nice.org.uk or with the Governance and Compliance team to establish whether a procedure has been notified or guidance published by NICE.

3.3.4 Clinicians wishing to introduce into the Trust a new clinical technique or procedure not previously undertaken before in the organisation must seek approval in accordance with this Policy.

3.3.5 When requested by NICE, clinicians must supply the information and data collection for all patients under the relevant Interventional Procedures Programme. The Data Protection Act and guidelines will govern the collection of data from patients.

3.3.6 The lead clinician is responsible for co-ordinating all aspects of the process including application preparation, local approval and signoff, application submission to QSAG, acting on the outcomes of business cases submitted for approval, and completing and reporting on subsequent audits of the new procedure/technique.

3.4 Quality and Safety Advisory Group (QSAG)

3.4.1 QSAG will consider applications from clinicians for the introduction of new clinical techniques and procedures within the Trust and decide on their approval or otherwise.

3.4.2 In agreeing to the introduction of a new clinical technique or procedure, QSAG will review a fully completed new procedure or technique application template presented by the applicant. The application must include consideration of the risks and benefits (including information for patients), documented training and competency assessment, the extent of authorisation to conduct the new procedure or technique, and audit and monitoring of patient outcomes. Further training and, or supervised mentorship or care guidance (e.g., a protocol or pathway) may be required by QSAG prior to approving the application.

3.4.3 If the procedure is the subject of NICE guidance, QSAG must consider whether the proposed use of the procedure complies with the guidance before approving it.

3.4.4 If a significant or unexpected incident occurs in association with a new clinical technique or procedure subject to this policy, it must be reported orally at the earliest opportunity by the clinician undertaking the procedure to the Clinical Director for the Directorate, the Divisional Medical Director and the Trust Chief Medical Office, and in writing through completion of a Datix incident report. No further similar procedures must subsequently be undertaken without the approval of the Trust Chief Medical Officer.

3.5 The Governance Department

3.5.1 The QSAG Administrator within the Governance Department will maintain a record of all applications for approved new procedures and techniques and a schedule of audit and monitoring to be reported to QSAG.

3.6 Directorate Management Team and Governance Group

3.6.1 The Directorate Management Team must monitor the implementation of the new procedure or technique and the outcomes and results of any audits via the divisional governance meeting. The Directorate Management Team must implement the Trust risk management process in regard to the reporting and investigation of adverse incidents and the management and appropriate escalation of any resultant risks.

3.6.2 The Group or Directorate Manager must monitor numbers and income to ensure costs are covered within the timeframe identified in the application

3.7 Divisional Management Team

3.7.1 The Divisional Management Team is responsible for final approval and sign-off of the new procedure application prior to presentation to QSAG. This includes the clinical and financial proposals within the application.

4.0 Policy Detail

4.1 A clinician wishing to undertake a new clinical technique or procedure must discuss the proposal with all appropriate colleagues internal and, if appropriate, external to the Trust.

4.2 The clinician intending to carry out the new clinical technique or procedure must complete an application form (Appendix 1) and forward this to the Clinical Director.

4.3 Upon receipt of the completed application form from the clinician, the Clinical Director will discuss the proposal with the relevant Lead Clinician (if not the applicant), the Directorate Management Team and Governance Group, the Divisional Management Team, and, if appropriate the relevant commissioning body.

4.4 If necessary, the Clinical Director must also seek further guidance from the Research & Development Directorate.

4.5 If supportive of the application, the Clinical Director must seek formal approval by forwarding the application form to the Divisional Medical Director for sign-off by the Divisional Management Team (refer appendix 2). The Clinical Director and the relevant clinician will be invited to present the proposal to the next available QSAG.

4.6 If the procedure is the subject of NICE guidance, the proposer must consider whether the proposed use of the procedure complies with the guidance. QSAG will consider this as part of the application process before approving the new procedure.

4.7 If no NICE guidance on the procedure is available or if NICE does not support the use of the procedure, QSAG will only approve its use if the following criteria have been met.

- The clinician undertaking the procedure has met externally set standards of training and can provide evidence of that training.
- All patients offered the procedure must be told of the special status or the lack of experience of its use. This must be done as part of the consent process and must be clearly recorded on the consent form and in any patient information leaflet. Patients must be told if the procedure's safety and efficacy are uncertain and be informed about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment.
- QSAG 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.

4.8 QSAG may return the proposal if not satisfied but applications may be re-submitted following appropriate amendment. N.B. approved applications will only apply to those identified to carry out the new procedure on the application form. The application must clearly state the staff who will undertake the procedure.

4.9 Prior to the introduction of a new clinical technique or procedure, the Trust will need to ensure that funding is in place to cover the costs (*this must include costs incurred by services outside the Trust, e.g. community services*). They must be

comprehensive (e.g., additional procedural time, training, and extended length of stay etc.) and not simply the cost of any new device or consumable. All savings must be clearly identified; where initial expenditure is to be received from future savings, full details of this including timescales must be provided. The financial implications must be set out within the application form (Appendix 1).

4.10 A business case must then be taken to the Contracting and Commissioning Group to ensure any costs are covered by the commissioners as part of the contracting process. The Contracting and Commissioning group must be informed if the introduction of a new procedure or technique is likely to attract a reduced or increased Payment by Result (PBR) tariff. This policy must be followed even if there are no financial implications to the introduction of a new clinical technique or procedure

4.11 The Clinical Director or Clinical lead must inform the relevant clinicians and other colleagues of the approval from QSAG and Contracting and Commissioning Forum (as appropriate) and agree a local implementation plan to cover the following issues.

- **Communication -** it is vital that prior to the introduction of any new clinical technique or procedure, the intentions and implications are communicated to the whole of the multi-disciplinary team. Consideration must be given to all the services affected, including general practitioners, community nursing and therapy staff.
- **Training and expertise** – the whole multi-disciplinary team must be involved in training for the introduction of the new clinical technique or procedure. Procedures needing to be developed must follow the OP1 Policy (*Development and control of policy and procedural documents*) format and approval process. QSAG will need to be assured that the responsible clinicians have received adequate and appropriate training and are competent to perform the procedure. If there is a need for an outside expert to support the clinician (e.g., a proctor) this must be clearly documented on the application form and the necessary honorary contracts put in place. Training records (including competency documents) for those authorised to carry out the new procedure or technique must be kept within the individual's personal file where appropriate; it must be updated on the delegated consent training record.
- **Consent** – if the new clinical technique or procedure is not supported by NICE guidelines, the patient must be told prior to being asked to give formal consent. Patients must be told if the procedure's safety and efficacy may be uncertain, and must be informed about the anticipated benefits and possible adverse effects of this treatment and alternatives, including no treatment. If written consent is not usually required for the standard procedure, consideration must be given to seeking written consent as a means of documenting the information given to the patient and their agreement to it. The information given to the patient must be recorded in the clinical record and in the letter to the GP. A copy of that letter should be offered to the patient. Patients must be given the choice to have other alternative treatments where available.
- Each new application must be subject to a clinical audit, the results of which must be presented to QSAG.

4.12 The only exception to the above process is when the procedure is being used within a protocol approved by the Health Research Authority (HRA) which incorporates Research Ethics Committee (REC). In this case, notification to NICE is not needed where the procedure is part of an HRA/REC approved research study. Use of the procedure outside the clinical trial protocol must only occur after approval from QSAG as set out above.

4.13 It is recognised that in rare circumstances, where no other treatment options exist, there may be a need to use a new clinical technique or procedure in a clinical emergency so as not to place a patient at serious risk. Under these circumstances, clinicians must seek the advice of the Clinical Director and the Chief Medical Officer, who will decide whether the intervention is deemed appropriate in these circumstances. The clinician will then follow the process above for the approval of the new clinical technique or procedure in routine and, or future emergency situations (Appendix 2).

5.0 Financial Risk Assessment

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

6.0 Equality Impact Assessment (EIA)

EIA has been completed; there are no impacts that affect personal protective characteristics of individuals.

7.0 Maintenance

The policy will be reviewed at least 3-yearly.

8.0 Communication and Training

This policy will be communicated via Trust Brief and via local governance processes. The Policy will be published on the intranet.

Advice/instruction on the application of this policy is available from Governance department on extension 85114.

9.0 Audit Process

9.1 The Trust's Chief Medical Officer will monitor implementation of the process for introducing new clinical techniques and procedures into the organization.

9.2 The relevant Directorate Governance Group will monitor delivery of the local plan developed to ensure the effective implementation of a new clinical technique or procedure.

9.3 The relevant Directorate Governance Group will review data on clinical outcomes captured through clinical audit and review continued use of the new clinical technique or procedure in line with OP45 Clinical Audit & Effectiveness Policy.

9.4 A progress (audit) report will be undertaken for each new procedure by the lead clinician or delegated person. It will be decided by QSAG, at point of approval, whether that report requires presentation at QSAG or the relevant directorate.

Criterion	Lead	Monitoring method	Frequency	Committee
Monitoring of follow up audits of approved new procedures or techniques	Governance administration	Maintain schedule of new procedures/techniques approved and dates for review.	6 monthly	Quality & Safety Advisory Group
Monitoring of documentation to support application approval.	Governance administration/ Local managers	QSAG review documentation supporting application approval during the approval process	As required	Quality & Safety Advisory Group

10.0 References

This policy takes into consideration the work of the National Institute for Clinical Excellence (NICE) Interventional Procedure Programme as directed on the NICE website www.nice.org.uk

Reference Number and Policy name: OP95 - Introduction of New Clinical Techniques and Interventional Procedures	**Version:** June 2022 V7	**Status:** Final	**Author: Healthcare Governance Manager** **Director Sponsor: Chief Medical Officer**

Version / Amendment History	Version	Date	Author	Reason
	V1	April 2006	Governance Lead	Introduction
	V2	March 2008	Governance Lead	Brief reference / description as to why an amendment has been made
	V3	Oct 2009	Governance Lead	Review
	V4	Oct 2012	Trust Governance standards lead	Review
	V5	January 2016	Head of Governance and Legal Services	Update in line with Trust OP1 policy format, refinements to application form, addition to definition of new/interventional procedure, clarification of responsibilities and accountabilities.
	V6	April 2019	Healthcare Governance Manager	Review
	V6.1	March 2020	Healthcare Governance Manager	2.2 - Sub-point 2 amendment to reference to extended roles
	V6.2	March 2022	Healthcare Governance Manager	Reviewed by Chief Medical Officer – Extended to July 2022

				pending full review
	V7	July 2022	Healthcare Governance Manager	Review

Intended Recipients: All Clinical staff, staff supporting/working within clinical areas and all management.	
Consultation Group / Role Titles and Date: Trust Policy Group (including Deputy Chief Nurse, Divisional Nurses, Medical member of Policy Group)	
Name and date of Trust level group where reviewed	Trust Policy Group – August 2022
Name and date of final approval committee	Trust Management Committee – September 2022
Date of Policy issue	September 2022
Review Date and Frequency (standard review frequency is 3-yearly unless otherwise indicated)	August 2025
Training and Dissemination: Policy existence notified at Senior manager brief, Policy guidance provided through Healthcare Governance managers and Governance Officers.	
To be read in conjunction with: HS 11 Management of Medical Devices Policy for authorisation on the new medical device where the new procedure involves a new medical device or equipment. Refer also to the limits of competency statement within Induction.	
Initial Equality Impact Assessment (all policies): **Completed Yes** **Full Equality Impact assessment (as required):** **Completed NA** If you require this document in an alternative format e.g., larger print please contact Central Governance Department on Ext 5114.	
Monitoring arrangements and Committee	6 monthly monitoring of approved procedures and reviews. 6 monthly sample monitoring of necessary documentation and local training records (Quality & Safety Advisory Group)
Document summary This policy describes the review and approval process to be applied by all staff prior to the introduction of a new clinical technique or interventional procedure into practice.	
Key words for intranet searching purposes:	

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version OP95 V7	**Introduction of New Clinical Techniques & Interventional Procedures**	
Reviewing Group Trust Policy Group QSAG		**Date reviewed: July 2022**
Implementation lead: Print name and contact details		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	**N/A**	**N/A**
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	**N/A**	**N/A**
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	**N/A**	**N/A**
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	**N/A**	**N/A**
Financial cost implementation Consider Business case development	**N/A**	**N/A**
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation	**N/A**	**N/A**

The Royal Wolverhampton NHS
NHS Trust

OP95 Appendix 1

Application to Introduce a New Clinical Technique or Procedure

1.	**Name of applicant/s *[this should be the clinician/s intending to carry out the new clinical technique or procedure]* Approved applications will only apply to those identified to carry out the new procedure below. The application must clearly state the staff who will undertake the procedure.**
Please include Staff Names and role titles for the persons undertaking this procedure. Please note: only those named in this application will be authorised to undertake this new procedure/technique.	
2.	**Title of the new clinical technique or procedure**
Please complete	
2.1	**Include a definition, if applicable**
Please complete if applicable	
2.2	**Brief description of what is involved in the clinical technique or procedure**
Please complete	
3.	**NICE status, please tick: see www.nice.org.uk / ip**

Guidance issued – safety and efficacy appears adequate for use with the normal arrangements for consent, audit and clinical governance. If yes state name of guidance/number:	☐
Guidance issued – deemed not safe/NICE do not support State name of guidance/number and brief rationale for status:	☐
Part of an approved research programme – requires approval by the R&D Directorate and HRA or **requires special arrangements** for audit / evaluation in accordance with NICE requirements.	☐
No guidance issued – see paragraph 8.10	☐
If none of the above apply please state:	☐
Is a business case required to implement the new procedure/technique? If so please include costings in section 15 below:	☐

4. Has this proposed new clinical technique or procedure previously been performed:	
At Royal Wolverhampton NHS Trust If yes state circumstances e.g. clinical emergency under proctor, within research trial etc.	Yes ☐ No ☐
4.1 Has the proposed new clinical technique or procedure previously been observed and performed by the applicant?	
If YES, where? *Please identify where the procedure has been observed or performed.*	Yes ☐ No ☐
How many times observed / performed by the applicant?	**Observed** ☐ **Performed** ☐
5. Is research evidence available regarding the effectiveness / safety of this new clinical technique or procedure?	
If **Yes**, please provide details:	Yes ☐ No ☐
A. Research paper reference[s]:	
B. Effective Health Care Bulletin:	
C. NICE Guidance:	
6. Does the proposed clinical technique or procedure replace any existing ones?	
If YES, please state what is being replaced:	Yes ☐ No ☐
7. Has the proposed clinical technique or procedure been discussed with:	
All appropriate Clinical or Divisional Medical Directors – especially in the case of multi-professional working:	Yes ☐ No ☐

Other relevant colleagues – internal and external to the Trust	Yes ☐ No ☐
If YES - who?	

8. Describe the benefits to the patient of the proposed clinical technique or procedure.

9. Describe any risks to the patient associated with the proposed clinical technique or procedure.

10. Training

a. Is the applicant and/or applicant(s) *(those named in Section 1)* trained to carry out the procedure?

Yes ☐ No ☐

b. If yes, what evidence of training is available for each applicant? *(Evidence must be available for all staff named in section 1)?*

c. Are all other members of staff involved in the procedure trained to carry out the procedure?

- ❑ Yes
- ❑ No
- ❑ N /A

d. If yes, what is their evidence of training?

e. If training is required, please confirm how this will it be provided for:

- ❑ The applicant(s):
- ❑ Other members of staff involved:

IMPORTANT – Copies of training and competency records for all staff must be kept within individual personal files.

11. What are the additional competencies required and for whom? How will these be met? (describe competency assessment for the applicant or others involved)

12. Describe the proposed informed consent process to be put in place: (consider any necessary updates needed to delegated consent lists)

13. Has an information leaflet been produced to support informed consent? (where the new procedure/technique is not supported by NICE this must be stated in the leaflet)

Yes ☐ No ☐

14. Clinical Audit / Evaluation: (in section c below please describe the essential elements of the audit/monitoring to be undertaken)

a. How many patients will be treated in the first instance?

b. How will patients be selected for treatment?

- ❑ Random
- ❑ Elective
- ❑ Non elective
- ❑ Other Please detail.

c. How do you propose to audit the use and effectiveness of the new procedure?

Audit undertaken by whom:

Audit undertaken by when:

Has this audit been added to the Directorate Clinical Audit Plan?

d. Has current practice been audited to enable later comparison with the new procedure?

15. Cost Benefit Analysis – Please state the total cost per patient of:

Has a business case been approved for any extra costs:	Yes ☐ No ☐
Costs Current technique / procedure: HRG Tariff	£ £

Cost Proposed technique / procedure: HRG Tariff	£ £
Will there be a reduction or increase in current Tariff: Any reduction/increase in Tariff must be notified to the Contracting and Commissioning Group	Yes ☐ No ☐
Total number of patients to be treated:	☐
Is Technique affordable:	Yes ☐ No ☐

16. Signatures required to validate the application (For application from Corporate areas sign off is to be from the service lead/Head of Department, Professional lead and Director responsible for the Corporate Service):

Specialty Lead Clinician [if not the applicant] Approved: Signature: Date:	Yes ☐ No ☐
Clinical Director/ Professional lead [if not the Lead Clinician/ applicant] Approved: Signature: Date:	Yes ☐ No ☐
Divisional Medical Director [if not the applicant] Approved: Signature: Date:	Yes ☐ No ☐
Divisional Manager (Deputy COO) Approved: Signature: Date:	Yes ☐ No ☐

Divisional Head of Nursing/Head of Midwifery Approved: Signature: Date:	Yes ☐ No ☐
OUTCOME OF SUBMISSION TO THE QUALITY & SAFETY ADVISORY GROUP (QSAG)	
Chair of the Quality and Safety Advisory Group Approved: If not approved, reason: Signature: Date:	Yes ☐ No ☐

Appendix 2

Flowchart to Follow When Implementing a New Procedure or Technique within the Trust